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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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DREW SCIENTIFIC, INC., : 08 CV 1490 (AKH)  
: :  
Plaintiff, : :  
: :  
-v- : :  
: :  
POINTCARE TECHNOLOGIES, INC., : :  
: :  
Defendant. : :  
-----x

**REPLY DECLARATION  
OF KARL GU IN FURTHER  
SUPPORT OF MOTION FOR  
A PRELIMINARY INJUNCTION**

KARL GU deposes and says:

1. I am employed by Drew Scientific, Inc. ("Drew") as a software engineer.

Although I was not chosen by PointCare to be deposed in this lawsuit, I submit this Declaration in response to the new allegations asserted by PointCare Technologies, Inc. ("PointCare") in opposition to Drew's motion for a preliminary injunction.

2. Specifically, the purpose of this Declaration is twofold: first, to clarify the record as to PointCare's wholesale failures with respect to software for the High-Thoroughput ("HT") project, and second, to correct various misstatements asserted by PointCare employees in their affidavits that concern PointCare's responsibilities with respect to software and my involvement with the same.

**HT Software – the User Interface and CD4 Algorithm**

3. Beginning in June 2006, I was assigned to work with software engineers from PointCare with respect to our joint HT project with them. Specifically, I worked with Andrea Desrosiers, Jennifer Waite and Dorothy Branco on this project.

4. From the very beginning of the Drew/PointCare relationship in June 2006 until now, no one ever disputed that these PointCare software engineers were fully responsible for seeing to completion two critical aspects of the HT's software – the graphical User Interface ("UI") and the CD4 algorithm. For this reason, I was very surprised when the attorneys for Drew informed me last weekend that in opposing Drew's motion for a preliminary injunction, PointCare has for the first time apparently changed course and blamed me personally for its software deficiencies. As set forth at length below, I note at the outset that PointCare failed to complete both the UI and the CD4 algorithm, which rendered testing of the HT machine impossible.

5. On June 15, 2006, I drafted a memorandum to Donald Barry of PointCare to "outline the initial tasks for the PointCare software team to start work on the user interface part of the CD4 software." (A true and correct copy of this memorandum and the cover e-mail is annexed hereto as Exhibit 1). As I was working overtime to complete an unrelated, pre-existing Drew project and had a pre-planned family vacation, I explained that I would not be able to provide much other assistance during this "3 to 4 week" period. (Id.)

6. On July 13 and 14, 2006, I met with Mr. Barry and the three PointCare software engineers at PointCare's Marlborough, Massachusetts headquarters. During that meeting we discussed the fact that PointCare was responsible for completing the UI and the CD4 algorithm. As a token of good faith, I expressed that I would be more than happy to provide PointCare with

help in working on these issues if the need ever arose. At no time did I ever state that I would be "responsible" for them, however. Nor do I know of any instance in which anyone ever made such a representation.

7. Over a month later, I received an e-mail from Jennifer Waite dated August 16, 2006, in which she stated "I'm really only just starting to get my feet wet this week because I've been busy finishing up some other projects." (A true and correct copy of this e-mail is annexed hereto as Exhibit 2). Her e-mail included a "tentative schedule" for software work, with deadlines extending to September 30, 2006. (Id.)

8. On September 7, 2006, Andrea Desrosiers sent me an e-mail reaffirming that PointCare was responsible for the CD4 algorithm. (A true and correct copy of this e-mail is annexed hereto as Exhibit 3). She stated: "My computational scientist, Dorothy [Branco], has begun to look at the FCS data we are currently acquiring from the Excell we have here. She will modify the current algorithm for analyzing the Excell data." (emphasis added).

9. From the outset, PointCare's progress with respect to both the UI and the CD4 algorithm was very slow. However, I frequently spoke with PointCare's software engineers by telephone and tried to offer my support by answering any questions they may have had. On December 13, 2006, Andrea Desrosiers and Jennifer Waite traveled to Drew's Dallas headquarters and met with me, my colleague William Ross, and Jason Werner, who is a software developer and consultant for Capsher Technology ("Capsher"). Capsher was hired by Drew in late 2006 to help Drew with the service software. Critically, PointCare (not Drew) then hired Capsher in early 2007 to assist them with the development of the CD4 algorithm.

10. At this December 13 meeting, Ms. Desrosiers reported to me that the UI software was "close to 50% done" and that PointCare estimated that they would finish the UI by the "end

of January 2007." I was concerned about PointCare's delays, and suggested that they bring in additional resources to ensure that the UI was completed. I included Ms. Desrosiers' "estimate" and my recommendation in the December 13, 2006 meeting minutes that I circulated to, among others, Ms. Desrosiers, Ms. Waite, and Mr. Barry. (A true and correct copy of these minutes with a cover e-mail are annexed hereto as Exhibit 4). At no time did anyone ever state that my meeting minutes were inaccurate.

11. The CD4 algorithm and the UI were the focus of discussion at the December 13 meeting. Specifically, Ms. Desrosiers stated that she "will be working with another person from PointCare on implementing the discussed interface for the CD4 algorithm dll." (See id.) . She assured me that she "will make the CD4 dll run faster and not freeze the user interface." (Id.) Again because I was concerned about PointCare's lack of progress and wanted to move this joint venture forward, I offered to assist PointCare by answering any questions with respect to the same. PointCare's responsibility for the CD4 algorithm, along with my offer to help answer any questions, were explicitly incorporated into the meeting minutes that I circulated to PointCare. (Id.). As noted above, at no time did anyone ever state that my meeting minutes were inaccurate.

12. I immediately shared my growing concerns with my supervisor at Drew, Andrew Kenney. On December 13, 2006, Mr. Kenney emailed Doug Nickols and Frank Matuszak, both of Drew, and put my frustrations into writing. He wrote:

We are running into a problem with the work PC is doing on the software. It was due in September, then Thanksgiving, now January. This is looking like the critical path right now. Karl thinks they are spending more time in France than on our work and that they have been told to give C2 priority. They are expecting a June launch apparently! I have asked Gary [Young] to complain to Don [Barry] that this work is slipping badly.

(A true and correct copy of this e-mail is annexed hereto as Exhibit 5). The reference to "C2" in Mr. Kenney's email concerns C2 Diagnostics, a French company that was primarily responsible for manufacturing the Near Patient ("NP") device.

13. Nearly a month later, PointCare still had done nothing to allay my fears. On January 9, 2007, Jennifer Waite e-mailed me and stated: "I know it looks like there's a lot left to do...but I'm pretty confident I'll have all of the coding done by the end of the month. It might not necessarily work perfectly on the instrument right away." (A true and correct copy of this e-mail is annexed hereto as Exhibit 6).

14. Yet another month later, Ms. Waite emailed me on February 6, 2007 and said: "I'm planning on having all high priority tasks completed by Friday. Our CD4.dll might not be quite ready for action by then." (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 7). ("CD4.dll" is a shorthand reference to the CD4 algorithm). That same night, Mr. Barry acknowledged that "the delivery of the software is already a week late from the scheduled date" and inquired as to whether I anticipated any possible delays by Drew with respect to software integration "assuming that the software will be finished [by PointCare] by Friday."

(See id.).

15. Somewhat irked by Mr. Barry's inquiry, I responded in no uncertain terms: "If I cannot get the UI and the CD4 dll, it is impossible to do any further integration." (See id.).  
(Emphasis added).

16. Nonetheless, the UI and the CD4 algorithm were still not completed by PointCare. On February 20, 2007, I sent an e-mail to Mr. Barry and the three PointCare software engineers, and stated: "In summary, if PCT team believes that Jason [Werner] or me will be responsible for fixing all problems related with code produced by PCT team, this is really an unfortunate

confusion. I will offer some help if available.” (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 8).

17. On March 2, 2007, Ms. Waite informed me by e-mail that Capsher was going to “help [them] with the CD4.” (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 9). Again emphasizing that the CD4 algorithm was PointCare’s responsibility, I replied on March 5, 2007 and said that “once Capsher sort[s] out the problem, you may need to come to Dallas to work a few days to finish the integration.” (See id.)

18. On March 26, 2007, I was copied on an e-mail in which Ms. Waite admitted that “we have more work to do to fix the meat of the DLL functions...but we now [are] on our way!” (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 10). In order to keep my Drew colleagues updated, I forwarded her email to Mr. Kenney, Mr. Nickols and Mr. Young, and again noted that “it is down to PointCare to supply a version of the CD4 dll to go with the unit.” (Id.)

19. After many requests from me, Ms. Waite visited Drew’s Dallas facilities on April 22, 2007 to work on HT software. Critically, the UI and the CD4 algorithm both continued to have many software “bugs” during her visit to Dallas. She originally planned to stay in Dallas for four to five days, but her trip was extended due to the numerous software bugs. Indeed, when she left for Massachusetts on May 3, 2007, citing personal reasons for her (perhaps early) departure, the UI and the CD4 algorithm were both extremely unstable, and the glaring problems remained.

20. Incredibly, both the UI and the CD4 algorithm were still not completed on May 8, 2007, when Ms. Waite informed me that “Dorothy [Branco] won’t be available to work on the

DLL until a bit later this week . . . We should have it ready for you by early next week." (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 11).

21. Three days later, I was disappointed and somewhat angered when Ms. Waite e-mailed me on May 11, 2007 that "Dorothy is working on the implementation concurrently with a higher priority project." (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 12) (emphasis added). I forwarded Ms. Waite's email to Mr. Kenney, Mr. Nickols and Mr. Young and expressed my profound frustration:

After all the help I gave to PointCare, I was expecting in a couple of weeks to have a CD4 software ready for validation. Originally I thought PointCare is late for another one week for the part I am requesting. It seems to me that I did not really understand what's going on in their side. They are working on a higher priority project as they said in the mail.

(A true and correct copy of this e-mail chain is annexed hereto as Exhibit 13).

22. This "higher priority project" was revealed to me in an e-mail from Peter Hansen dated May 29, 2007, in which he announced: "I will have to stop HT software work at PCT for approximately 2 ½ weeks from today in order to meet long standing, scheduled obligations for our software group on the NOW." (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 14). (The "NOW" refers to the NP device.)

23. In response, Mr. Nickols copied me on an e-mail dated May 30, 2007. He stated:

PointCare continues to fail to meet deadlines, falling short of our expectations. Dll software completion has slipped 6 months and counting. Hopefully, their cobbled together UI will be sufficient to move along. If it's not, please let me know immediately.

(See id.).

24. On June 1, 2007, Ms. Waite e-mailed me "a list of UI tasks that still need to be completed," which list included no less than ten items. (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 15). To my disbelief, she further stated: "I do not know at this

time when these tasks will be complete because for the next 2 weeks I will be working on our AuRICA NOW software validation which includes me going to France for a week." (Id.)

25. In light of this e-mail and Dr. Hansen's May 29, 2007 e-mail, it was abundantly clear to me that PointCare's entire software team had been reassigned to work on the "higher priority project" – which was PointCare's NP device. Although PointCare's software team was supposed to return to work on the HT project, they never did.

26. On June 8, 2007, Ms. Waite emailed me what she described as "a new CD4 DLL file, a new UI executable file, and the CD4 DLL integration document." (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 16). Although I was not optimistic, I told Mr. Young and Mr. Nickols about this development and stated that "we will start testing ASAP." (Id.) As a courtesy to Ms. Waite, I responded to her e-mail shortly after it was sent and, without reviewing the substance thereof, said that "William [Ross] will try the new software soon." (See Exhibit 10 to Waite Aff.).

27. That same day, I responded again to Ms. Waite in writing and told her that after an initial review, I had noticed that the "classification for CD4 is set as 0 all the time when store[d] to disk," and noted that "I am not sure why you have any junk data." (A true and correct copy of this e-mail chain is annexed hereto as Exhibit 17). This was in response to Ms. Waite's question in her June 8 e-mail about a possible problem with Drew's software, which problem did not exist. When I explained the same, she acknowledged by e-mail that she had made a mistake. (See id.)

28. As promised, in short order, my colleague William Ross and I reviewed the CD4 algorithm and UI that PointCare provided to me on June 8, 2007, and determined that they were incomplete and wholly non-functional – they were repeatedly crashing and were extremely

unstable. I believe that this crashing was due to a critical problem with the CD4 algorithm that PointCare could never solve – it was unable to calculate CD4 positive white cell lymphocytes as a percentage of the total lymphocyte population being tested, and divisions of zero were rendering the data entirely useless. (A number divided by zero is indeterminable). Indeed, PointCare's failure to finish the software work that was its sole responsibility has rendered it impossible to test the HT machine to the extent that might otherwise be desirable.

29. I communicated my findings to Ms. Waite by telephone sometime in early June, 2007. In light of the fatal deficiencies with respect to the CD4 algorithm and the UI, which had persisted for close to one year, I saw no reason to prepare a written report as to the same.

30. Subsequently, in November 2007 I reviewed all the software sources from the PointCare FTP site that Ms. Waite had provided to me. It appears to me that the critical CD4 algorithm work was stopped in early June of 2007 and that no work has been done on the important UI since August 2007.

31. As noted above, PointCare's failure to finish the software work that was its responsibility has rendered it entirely impossible to test the HT machine to the extent that might otherwise be desirable. I related this fact to Dr. Herbert Chow when he came to Drew's facilities in Dallas to test the HT in November 2007. Dr. Chow's test results confirmed these critical software shortcomings.

#### Misstatements in PointCare Affidavits

32. For the sake of brevity, I would like to incorporate my sworn statements above in response to all assertions made by PointCare in its April 27, 2008 Opposition to Drew's motion for a preliminary injunction that concern HT software and/or my involvement with the same, including the five Affidavits and the Memorandum of Law therewith. However, to further

clarify the record, I address below relevant paragraphs from the Affidavits of Jennifer Waite, Andrea Desrosiers, and Peter Hansen that I found to be particularly troubling. To the extent that such allegations are repeated by or among PointCare's affiants, I have addressed them directly only once in this Declaration.

### **Desrosiers Affidavit**

33. In Andrea Desrosiers' Affidavit dated April 25, 2008 (the "Desrosiers Aff."), Ms. Desrosiers claims in relevant part that "Drew first needed to complete the instrument control and service software to develop the HT engineering prototype." (See Desrosiers Aff. ¶¶ 3-4). I believe this to be a very misleading sentence. First, the instrument control is fully functional and has been since late 2006. Second, and more importantly, the "service software" depends on the CD4 algorithm that PointCare was responsible for completing, and the testing of the machine depends on the functionality of the UI, neither of which PointCare ever completed. PointCare's failure to finish the CD4 algorithm and UI has rendered it impossible to test the HT machine. Any statement to the contrary is patently untrue.

34. Ms. Desrosiers further states that "[w]ith respect to PointCare's obligations to develop the user interface software and the CD4 algorithm, PointCare effectively completed these in a timely manner." (Id. at ¶ 5). (emphasis added). This is absolutely not true. I do not know what Ms. Desrosiers means in using the qualifier "effectively," but I am certain that the CD4 algorithm and UI were never completed.

35. Additionally, she represents that she is "not aware of any failure by PointCare's HT software team that would have hindered Drew's HT prototype development." (Id. at ¶ 5). With all due respect to Ms. Desrosiers, I believe that if she is not aware of any such failure, it is because she was entirely focused on developing the NP device to the detriment of the HT.

Indeed, dating back to June 2006 I am aware of no instance in which Ms. Desrosiers contributed to solving a single problem with respect to the HT software. In fact, her subordinate, Ms. Waite, frequently telephoned me for help in resolving HT software issues instead of asking her boss for assistance. To the extent I could help Ms. Waite, I was more than happy to do the same, even though it was never my responsibility.

36. Ms. Desrosiers then states that she “learned from [me] that [I] wanted to create a ‘dll’ (dynamic link library) wrapper for PointCare’s CD4 algorithm,” that I “emailed [her] a preliminary dll several months later which did not even contain PointCare’s algorithm,” and that I “later refused to finish the dll or even help PointCare finish it (despite previously committing to lead the effort).” (Id. at ¶ 6). These statements are entirely without basis in fact. In the spirit of cooperation in furtherance of our joint venture, I did offer to provide a dll skeleton for PointCare to incorporate their CD4 algorithm, but this dll skeleton was meant to be used by PointCare as a reference. I never in any way expressed that this reference would contain PointCare’s algorithm (which was never completed), and similarly I never “committ[ed] to lead the effort” for the CD4 algorithm. At all times the CD4 algorithm was PointCare’s responsibility. Any guidance that I provided them was done in good faith, and could not possibly have been interpreted to signal that Drew was somehow responsible for the completion of the CD4 algorithm.

37. Finally, Ms. Desrosiers’ statement that I “refused to provide PointCare with the Drew source code for the instrument control and service software” has no bearing whatsoever on PointCare’s failure to develop the CD4 algorithm. (Id. at ¶ 6). Simply put, my understanding was that Drew’s source code was highly confidential, and sharing it with PointCare would in no way advance their efforts to complete the CD4 algorithm. This source code serves an entirely different, unrelated purpose, and has nothing to do with the CD4 algorithm. Moreover, I never

asked Ms. Desrosiers for PointCare's source code, and despite her "good faith" decision to give it to me in July 2006, I did not feel that it was appropriate for me to review the same at that time. I further note that Ms. Desrosiers gave me PointCare's old AURICA source code because she wanted me to help resolve a critical deficiency with its algorithm. Specifically, its data computation was very inefficient and she was looking for my help to suggest ways to speed it up. I provided help to the best of my knowledge and ability.

**Waite Affidavit**

38. I specifically incorporate by reference herein my sworn statements above to the extent that they address any and all statements in Jennifer M. Waite's Affidavit dated April 25, 2008. (the "Waite Aff."), and I specifically refer to my earlier statement in paragraph 33 hereof about the "service software."

39. Ms. Waite states that "[d]uring August and September 2006, Mr. Gu and I were in frequent contact about many aspects of the user interface software and corresponding database development and he seemed content with my progress on my assigned tasks." (See Waite Aff. at ¶ 6). Although I was content with Ms. Waite's progress in those very first months of work on the UI, I later became very frustrated by PointCare's wholesale failure to complete the same. As noted above, nine months later, on June 1, 2007, Ms. Waite e-mailed me "a list of UI tasks that still need to be completed," which list included no less than ten items. (See Exhibit 15 hereto). Moreover, any contentment that I expressed with respect to initial UI progress did not reflect any satisfaction on my part with PointCare's work on the more important CD4 algorithm, even in the summer of 2006.

40. Ms. Waite further states that in the end of January, 2007, "the task of integrating (i.e., creating the links between) [her] user interface software and the CD4 algorithm developed

by fellow PointCare colleague Dorothy Branco, was yet to be completed.” (See Waite Aff. at ¶ 11). This is undoubtedly true, because both the UI and the CD4 algorithm are not complete today, much less 15 months ago. Her suggestion that I and Mr. Werner were “supposed to be leading this integration effort” makes no sense whatsoever, since one cannot successfully integrate two wholly deficient aspects of software. (Id.) In layman’s terms, this is tantamount to demanding a glass of chocolate milk but depriving your server access to both chocolate and milk.

41. Ms. Waite did put some “source code files onto PointCare’s FTP server,” but as noted above, I was uncomfortable reviewing PointCare’s proprietary new CD4 algorithm source code, and did not download the same at the time. (Id. at ¶ 12). (When in November 2007 I reviewed the software sources from the PointCare FTP site, I learned that the critical CD4 algorithm work was stopped in early June of 2007 and that no work has been done on the important UI since August 2007.) I do not believe that sharing of unrelated source code was in any way relevant to advancing the CD4 algorithm, and I do not understand PointCare’s repeated references to this issue in their Opposition.

42. Furthermore, Ms. Waite’s suggestion that she was making “it easier for [me] to help [PointCare] debug the problems” is misleading. (Id. at ¶ 12). Any help that I offered to provide PointCare with respect to the CD4 algorithm was done as part of a good faith effort to advance the interests of the joint venture. It was never my responsibility – nor Drew’s responsibility – to do the same, although I did what I could. I did refer them to Capsher, which was hired by PointCare to help them with the CD4 algorithm.

43. Critically, Ms. Waite’s recount of her April 22 to May 3, 2007 visit to Drew’s Dallas facilities is extremely misleading. (Id. at ¶¶ 14-15). She states that the “software was at a point where Drew could start its software validation testing.” (Id. at ¶¶ 15-16). This could not be

further from the truth. The UI and the CD4 algorithm both continued to have many software "bugs" as of May 3, and those bugs were not even fixed in PointCare's most recent software that was sent to me on June 8, 2007. Her representations to the contrary are untrue.

44. I also note that the "STAT Sample" feature referenced by Ms. Waite is a wholly non-essential element of the UI. (*Id.* at ¶ 21). Her reference thereto does nothing to change the critical fact that PointCare failed in its responsibility to complete the UI.

**Hansen Affidavit**

45. I specifically incorporate by reference herein my sworn statements above to the extent that they address any and all statements in W. Peter Hansen's Affidavit dated April 25, 2008. (the "Hansen Aff.").

46. Dr. Hansen states that in a June 2006 meeting, I "objected to Drew sharing its secret source code with PointCare and that meant [I] would have to manage the PointCare staff for HT software." (See Hansen Aff." at ¶ 76). This statement is absurd. First of all, I believe this meeting occurred in late 2006 and was a conference call with Dr. Hansen, Ms. Desrosiers, myself and others. As noted above, my objection to the sharing of any hematology calculation source code between Drew and PointCare was because of my understanding that Drew's hematology calculation source code was highly confidential, and sharing this unrelated source code with PointCare would in no way advance their efforts to complete the CD4 algorithm. Indeed, I believed that the sharing of the hematology calculation source code would only create unnecessary confusion. Second, I note that during the same conference call with Dr. Hansen, Ms. Desrosiers unequivocally stated that she did not need Drew's hematology calculation source code in order to complete PointCare's responsibilities with respect to the CD4 algorithm and the

UI. Simply put, there is no “secret source code” that would prevent PointCare from completing the CD4 algorithm and the UI.

47. I never said that I “would have to manage the PointCare staff for HT software” to Dr. Hansen or to anyone else. As described at length above, at all times it was abundantly clear that PointCare was responsible for seeing the critical CD4 algorithm and UI to completion.

48. Dr. Hansen next states that “[i]n the discussion that followed, [he] learned that Mr. Gu worked from home a lot (two days a week).” (See Hansen Aff. at ¶ 77). Again, this makes no sense, because I did not begin working from home until late February of 2007, a full 8 months after the June 2006 meeting referenced above. Moreover, my working from home has never in any way affected my ability to further the Drew/PointCare joint venture. From the outset, I was 100 percent available to PointCare when I worked from home, just as I was during the days that I primarily worked from Drew’s Dallas facilities.

49. Dr. Hansen’s claim that he “agreed to having [me] manage the HT software development . . . because [I] said Drew must keep [its] Excell22 software secret” is as nonsensical as it is unsupported by reality. (See Hansen Aff at ¶ 80). The same is true of the notion that “[t]his important condition put on the project by Mr. Gu meant that only [I] would know how to make any PointCare software communicate properly with the HT” and that “only [I] would be capable of ‘software integration’ for the HT project.” (Id.) I never said these things to anyone, let alone to Dr. Hansen, and nor would I say them because they are inaccurate. As stated above, my preference to not share Drew’s hematology calculation source code with PointCare had no bearing on the development of the CD4 algorithm or the UI. I flatly reject the inexplicable notion that because I had Drew’s source code, I was the only person who could “make any PointCare software communicate properly with the HT.”

50. Dr. Hansen's statements about my meeting with PointCare's software team in Marlborough on July 13 to 14, 2006 are also perplexing. (See Hansen Aff. at ¶¶ 82 to 84). He states that “[d]uring the meeting, [he] emphasized to Drew's engineering team that time to product launch was of the essence and part of the contract between Drew and PointCare,” and that he “made it clear to everyone that the timeline was a firm, contractual commitment.” (Id. at ¶¶ 83-84). At the outset, I note that I was the only person from Drew at this meeting, so I don't understand his reference to “Drew's engineering team.” Second, my recollection is that Dr. Hansen was not involved in that meeting, and thus he could not have mentioned the timeline.

51. Similarly, his representation that he has “first-hand knowledge that [I] waited a full month after the technical planning meeting to have [my] first meeting with [my] PointCare software engineers and even tell them what [I] wanted them to do” is untrue and irrelevant. (See Hansen Aff. at ¶ 85). In support of this proposition, he refers to the minutes of the July 13, 2006 meeting at PointCare, which meeting he has inexplicably deemed “belated.” (See Exhibit 9 to Hansen Aff.). Nowhere in those minutes does it attribute any delay to me, so this reference must have been included in error. As explained above, I had drafted a June 15, 2006 memorandum to Mr. Barry outlining “the initial tasks for the PointCare software team to start work on the user interface part of the CD4 software.” (See Exhibit 1 hereto). As I was working overtime to complete an unrelated, pre-existing Drew project and had a one week pre-planned family vacation, I explained that I would not be able to provide much assistance during this short “3 to 4 week” period. (Id.) However, this memo would serve to allow PointCare to begin to work on software tasks during my very brief unavailability.

**Conclusion**

For all of the reasons articulated herein, I respectfully submit this Reply Declaration in further support of Drew's motion for a preliminary injunction. I declare under penalty of perjury of the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Dated: April 30, 2008

  
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KARL GU

DM1\1322378.3

**EXHIBIT 1**

**From:** Karl Gu  
**Sent:** 6/15/2006 4:35:03 PM  
**To:** 'dbarry@pointcare.net'  
**CC:** Andrew Kenney - UK; Gary Young; 'phansen@pointcare.net'  
**Subject:** Emailing: EXCELL 22\_CD4 Software Initial task.pdf

Hi Don,

This is the task list as promised and subsequent emails will direct to you only as they contains documents that provide information to accomplish the tasks.

Regards,  
Karl

Attachment: EXCELL 22\_CD4 Software Initial task.pdf

Drew Scientific Inc.

## Memo

To: Donald Barry  
From: Karl Gu  
CC: Gary Young, Andrew Kenny, Peter Hansen  
Date: June 15, 2006  
Re: CD4 User Interface Initial Tasks

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As requested, I submit this memo to outline the initial tasks for the PointCare software team to start work on the user interface part of the CD4 software. The tasks are selected based on the following considerations:

- The time frame is 3 to 4 weeks from now.
- Initial tasks need to be simple and independent of instrument operation logic
- Not much help would be available from me for this period
- A general knowledge of existing EXCELL 22 instrument is essential
- Task priority in the scope of user interface
- All tasks are strictly limited to user interface
- Workload is about 5% or less of the total user interface work in my judgment.

The tasks are:

A. General knowledge of the EXCELL 22 analyser

Familiar with the EXCELL 22 analyser by running the analyser, reading the operator manual, then going through the menu from VB, all passwords are in the code, if blocked by a condition, just remove the condition in code

B. Development Tools

As the first step, we need to decide what development tools to use for this project. EXCELL 22 was developed back in 1999-2000 and we used Visual Studio V6.0, MS ACCESS 97, and Multilizer as the language tool.

B.1 If VB .Net or C#, how much time will be involved to convert the source?

B.2 If use a later version of ACCESS database, how much effort would be?

B.3 What language tool to use? Use .NET, no third party or in-house language tool needed

C. Tasks that independent of machine operation and can be assigned to individual developer

Tasks such as data presentation, transfer, and printing do not need an operating machine. CD 4 data can be hard coded in routine to generate display, print, transfer. Have some actual layout would help marketing people to make up their minds.

C.1 Generate results display by hard code CD 4 data

C.2 Generate results printout in similar way

Drew Scientific Inc.

C.3 Get to know data file format used in EXCELL 22, the FCS file V3.0, there might be more recent version. We need to find out if any update exist of the standard. Need to consider how we plan to add the addition CD 4 scatter data in FCS file.

C.4 Transfer protocol. EXCELL 22 use ASTM protocol and now the standards updated to CLSI standard. We need to find out what is the difference of ASTM and CLSI standards. Need to consider how to add the new CD4 test order and results to our application.

C.5 Detection of power outage. Find out what API to access UPS power status.

C.6 Generate menu tree according to supervisor/operate mode

D. WISH LIST

How to make the OVERALL UI looks like a Touch Screen application instead of menu driven app?

**EXHIBIT 2**

**From:** Karl Gu  
**Sent:** 8/16/2006 7:21:01 PM  
**To:** Jennifer Waite  
**CC:** Andrea Desrosiers; Don Barry; Andrew Kenney; Gary Young  
**Subject:** RE: AuRICA HT UI

Hi Jen,

The dates look good.

For the UPS, we need to know what type/brand/model of UPS and when the UPS is available for us to play with. Is Don responsible for this?

We may want you and/or Andrea come to Dallas mid of September to review what we have done and discuss how to implement the remaining functionality of the UI.

Regards,  
Karl

---

**From:** Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
**Sent:** Wednesday, August 16, 2006 12:32 PM  
**To:** Karl Gu  
**Cc:** Andrea Desrosiers; Don Barry  
**Subject:** AuRICA HT UI

Hi Karl,

I'm really only just starting to get my feet wet this week because I've been busy finishing up some other projects. I have come up with a tentative schedule. Please let me know what you think...

-jen

Task

Person Responsible

Date due

Modify Drew's DB document with new changes.

J. Waite

8/25/06

Populate DB with CD4 data.

J. Waite

8/25/06

Change Screen Menus w/o functionality.

J. Waite

9/5/2006

Generate Screen/Menu change document.

J. Waite

9/11/2006

Implement print functions.

J. Waite

9/15/2006

Build remaining functionality.

J. Waite/K. Gu

9/30/2006

Detection of power outage from within UI

J. Waite/K. Gu

TBD

Provide additional data for monitoring Mono center shift

A. Desrosiers/D. Barry

TBD

Get clarification about existence of TOF signal

D. Barry

TBD

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

tel: (508) 281-6926 x15

fax: (508) 281-6930

work: jwaite@pointcare.net

personal: jwaite@alum.wpi.edu

-----Original Message-----

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]

Sent: Wednesday, August 16, 2006 1:08 PM

To: Jennifer Waite

Subject: RE: Finished Meeting Minutes Doc

Hi Jen,

How are we doing for the UI? We need to fill the TBD with some dates to track the progress.

Regards,

Karl

---

From: Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
Sent: Wednesday, August 02, 2006 1:12 PM  
To: Karl Gu  
Subject: Finished Meeting Minutes Doc

Hi Karl,

Here is the copy of the finished meeting minutes. This version is going to be released through our QA system.

-Jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

tel: (508) 281-6926 x15

fax: (508) 281-6930

work: [jwaite@pointcare.net](mailto:jwaite@pointcare.net)

personal: [jwaite@alum.wpi.edu](mailto:jwaite@alum.wpi.edu)

**EXHIBIT 3**

**From:** Andrea Desrosiers  
**Sent:** 9/7/2006 2:14:45 PM  
**To:** Karl Gu  
**CC:**  
**Subject:** RE: cd4 algorithm doc

Hello Karl,

I have attached 2 documents. SRS-006 contains a summary of how our current CD4 algorithm works. The document refers to the cluster1.ini file and the FCS file header that contains the settings we use for the algorithm. The format of the cluster1.ini file, as well as the FCS file header, are described in SRS-005, pages 39 and following.

I understand that you retrieve the event data directly from the stream for your current gating algorithm, as opposed to reading the data in from the FCS file. My computational scientist, Dorothy, has begun to look at the FCS data we are currently acquiring from the Excell we have here. She will modify the current algorithm for analyzing the Excell data. Let me know if you would like some data files.

Sincerely,  
Andrea Desrosiers

---

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]  
Sent: Wednesday, September 06, 2006 6:16 PM  
To: Andrea Desrosiers  
Subject: cd4 algorithm doc

Hi Andrea,

During my visit to PointCare, I believe that you gave me a doc, which describes the current cd4 algorithm. However, I could not locate such a doc in my computer. Could you send the cd4 algorithm related docs to me?

Thank you,

Karl

Attachment: SRS-006 B Pointcare Algorithm Specifications.pdf  
Attachment: SRS-005 F Sequence Requirements Specification.pdf

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|  PointCare<br>Technologies Inc. | <b>SYSTEM REQUIREMENTS SPECIFICATION</b>             | Document Number:<br>SRS 006 | Rev.B |
| Effective Date:<br>3/3/2006  | AuRICA Algorithm and Flag Requirements Specification | Page 1 of 8                 |       |

| Rev | ECO    | Date      | Description                  |
|-----|--------|-----------|------------------------------|
| A   | E-0064 | 3/14/2005 | Initial Release              |
| B   | E-0226 | 3/3/2006  | New Lyse and Control changes |

| Name                | Signature | Date | Title                     | Approval Function |
|---------------------|-----------|------|---------------------------|-------------------|
| Andrea Desrosiers   |           |      | Software Developer        | Originator        |
| Jennifer Waite      |           |      | Software Developer        | Technical Review  |
| Don Barry           |           |      | Scientist                 | Technical Review  |
| Kassey Kalufkiewicz |           |      | Chief Operating Officer   | Marketing Review  |
| Maurice Doire       |           |      | Quality Assurance Manager | QA                |

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| Effective Date:<br>3/3/2006  | PointCare Algorithm and Flag Requirements<br>Specification | Page 2 of 8                 |       |

## FLOWCARE CD4 ALGORITHM AND FLAG SOFTWARE REQUIREMENTS

### 1. Introduction

- 1.1. This document describes software requirements for the Point Care Technologies AuRICA Automated Immune Hematology Analyzer data analysis package.

### 2. Scope

- 2.1. This document shall provide software requirements in enough depth to permit the construction of test cases that address all data analysis software functions.
- 2.2. This document applies to revision 2.0.5.0 of the algorithm which supports changes described in the Software Status Report NL-0018.

### 3. Applicable Documentation

- 3.1. SRS-002 AuRICA Software Requirements Specification
- 3.2. SRS-003 AuRICA Hazard Analysis
- 3.3. SRS-005 AuRICA Sequence Requirements Specification
- 3.4. NL-0018 Software Status Report

### 4. Algorithm Requirements

- 4.1. The algorithm shall be a free standing executable program callable either from within AuRICA software or from a windows command line during regression testing.
  - 4.1.1. The command line for the program shall be "cluster1.exe filename [M]" where filename refers to an FCS input file and the optional [M] parameter enables graphic visualization of the algorithm output for use during test and evaluation.
- 4.2. The Algorithm shall accept as input an FCS file with Forward Scatter High Peak (FSH), Forward Scatter Low Peak (FSL), Extinction Integral (EXI), Right Angle Scatter Integral (RAI), and Time of Flight (TOF) values for each event, as well as the time intervals during which events were counted, the number of events counted during each of these time intervals, the total acquisition time, the total number of digitized events, the fluid flow rate, and the nominal dispense volumes of the lyse, sheath, and sample.

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| Effective Date:<br>3/3/2006  | PointCare Algorithm and Flag Requirements<br>Specification | Page 3 of 8                 |       |

- 4.2.1. The FCS file shall contain settings that permit use of the algorithm with lysed whole blood or control materials.
- 4.2.2. A setting within the FCS file (PCTSampType) indicating whether the sample is a whole blood or a control material will determine which of the alternative settings shall be used by the algorithm.
- 4.2.3. Settings can also be provided by an initialization file. When the initialization file is present, settings from this file (SampleType) will be used instead of the settings in the FCS file.
- 4.3. The Algorithm shall return data in a comma separated value formatted file to be used either by the AuRICA software or Excel during regression testing.
- 4.3.1. Data Fields shall be, in left to right order, WBC count, Lymphocyte Count, Lymphocyte Percentage of WBC, CD4 positive count, and CD4 percentage of Lymphocytes, Flag character, and filename.
- 4.4. The Algorithm shall run “silently” (with no visual display) during use with the AuRICA software.
- 4.4.1. The Algorithm can run “visually” during use with the AuRICA software if the service parameter setting in the AuRICA database is set for visual display.
- 4.5. The Algorithm shall run “visually” during regression testing as an aid in gauging performance.
5. Analysis procedure
- 5.1. The flow data extracted from the FCS file (IDXCounterXXX and IDXTimerXXX, where XXX is a sequential integer with leading zeroes as necessary) shall be used to filter out all events which occur during a time interval identified as having anomalous flow characteristics.
- 5.1.1. Anomalous flow characteristics include a flow rate within the time interval that is less than one half of the average flow rate of the sample, or a flow rate within the time interval that is greater than four times the average flow rate of the sample.
- 5.1.2. All events within the time interval immediately following an interval containing anomalous flow characteristics are also filtered out.
- 5.2. A plot with FSH on the Y axis and FSL on the X axis shall then be constructed from the filtered FCS event data.

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| Effective Date:<br>3/3/2006  | PointCare Algorithm and Flag Requirements<br>Specification | Page 4 of 8                 |       |

5.3. All events falling inside a triangular region located in the lower left-hand corner of the plot, the dimensions of which are determined during instrument set-up, shall be marked as noise, and shall be excluded from all calculations in the subsequent analysis.

5.3.1. The points at which this triangle intersects the X and Y axes are defined by settings in the initialization file (FSL\_Thresh and FSH\_Thresh, respectively) or the FCS file (PCTFSLThresh and PCTFSHTThresh, respectively).

5.4. A density plot with FSH on the Y axis and TOF on the X axis shall be constructed from the filtered FCS event data.

5.5. A constrained search of the expected Lymphocyte area of the FSH/TOF plot shall be conducted to establish a set of local density maxima.

5.5.1. The expected Lymphocyte area is a rectangle defined by settings in the initialization file (X\_Center\_Max, X\_Center\_Min, Y\_Center\_Max, Y\_Center\_Min) or the FCS file (PCTXCenterMax, PCTXCenterMin, PCTYCenterMax, PCTYCenterMin).

5.6. The center of density (centroid) of the maxima shall be calculated using a weighted average of all the local density maxima.

5.7. An oval shall be constructed about the centroid.

5.7.1. The width of the oval shall be set to twice the distance from the centroid to the point to the left of the centroid at which the density falls to a small fraction of the total density.

5.7.2. The top of the oval is set to the distance from the centroid to the point above the centroid at which the density falls to a small fraction of the total density.

5.7.3. The bottom of the oval is set to the distance from the centroid to the point below the centroid at which the density falls to a small fraction of the total density.

5.8. The events inside of the oval shall be counted as Lymphocytes.

5.8.1. When the total number of counts inside the oval is less than 300, the top and bottom of the oval shall be set to a default height, and the width of the oval shall be set to a default width.

5.8.1.1. The default height and default width are determined during instrument set-up and are defined in the initialization file (Default\_Height and DefaultWidth, respectively) or in the FCS file (PCTDefaultHeight and PCTDefaultWidth, respectively).

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| Effective Date:<br>3/3/2006  | PointCare Algorithm and Flag Requirements<br>Specification | Page 5 of 8                 |       |

5.8.2. The events inside of the default oval shall be counted as Lymphocytes.

5.9. When settings in the initialization file (Silent) indicate that data is to be displayed, density plots shall be displayed with the contents of the oval highlighted.

5.10. White Blood Cells shall be counted as the sum of the Lymphocytes plus all of the events to the right of a vertical line tangent to the right-hand side of the oval.

5.11. The EXI and RAI values for the events inside of the oval shall be plotted with EXI on the Y axis and RAI on the X axis.

5.12. A line shall be drawn from the origin of the EXI/RAI plot to a position at the top of the plot. This position is called the separation angle.

5.12.1. The separation angle is the angle at which a plot of the "slant distances rate of change" as a function of the trial separation angle reaches a minimum, within a range from the start angle to the maximum angle.

5.12.1.1. The first trial separation angle (start angle) for the angle search shall be based on the angle that passes through the origin and the centroid of the EXI/RAI plot.

5.12.1.2. A range of trial separation angles is drawn in fixed increments that are based on the square root of the start angle.

5.12.1.3. For each trial separation angle, a wedge is constructed that is bounded on the left by the trial separation angle, and on the right by the next trial separation angle.

5.12.1.4. The "slant distance" of each event within this wedge is calculated.

5.12.1.4.1. The "slant distance" is defined as the distance from an event to a horizontal line  $y = y_0$ , where  $y_0$  is the y-coordinate of the centroid of the EXI/RAI plot, measured along an angle joining the event to the origin.

5.12.1.5. All the "slant distances" within a wedge are added up and divided by the accumulated sum of all the "slant distances" of all prior wedges to get the "slant distance rate of change".

5.12.2. The maximum trial angle shall be an integer multiple of the start angle that passes through the origin.

5.12.2.1. The maximum possible angle is set to 300.

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| Effective Date:<br>3/3/2006  | PointCare Algorithm and Flag Requirements<br>Specification | Page 6 of 8                 |       |

5.13. Events that fall to the right of this separation angle shall be counted as positive CD4 cells.

5.13.1. When settings in the initialization file (Silent) indicate that data is to be displayed, the plot shall be displayed with the positive CD4 events highlighted.

5.13.2. When settings in the initialization file (Silent) indicate that data is to be displayed, all counts and percentages shall be displayed.

## 6. Results Calibration

6.1. A correction shall be applied to all count values that accounts for the sample dilution and extrapolates counts to any undigitized events.

6.1.1. The final analyzed dilution shall be calculated from the nominal sample volume divided by the nominal sample, lyse, and sheath dispense volume settings in the initialization file (Sample\_Volume, Lyse\_Volume, and Sheath\_Volume, respectively) or in the FCS file (PCTSampleVolume, PCTLyseVolume, and PCTSsheathVolume, respectively).

6.1.2. The volume of sample analyzed shall be calculated by multiplying the analyzed dilution by the fluid flow rate and the total acquisition time indicated in the initialization file (FlowRate and Duration, respectively) or in the FCS file (PCTSampleRate and PCTDuration, respectively).

6.1.3. The number of events per analyzed volume shall be calculated by dividing the total number of events counted, defined in the initialization file (EventCount) or the FCS file (IDXEventCount), by the volume of sample analyzed.

6.1.4. The total number of digitized events shall be calculated by counting all the events in the FCS file with stable flow characteristics.

6.1.5. The number of events per analyzed volume is then divided by the total number of digitized events to get the count correction factor.

6.1.6. The percentage of digitized events is calculated by dividing the total number of digitized events by the total number of events defined in the initialization file (EventCount) or the FCS file (IDXEventCount).

6.2. Individual calibration slope and offset corrections that can be applied to WBC, Lymphocyte, and CD4 count values for whole blood or control materials shall be set in the initialization file (Wbc\_Coeff ,

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| Effective Date:<br>3/3/2006  | PointCare Algorithm and Flag Requirements<br>Specification | Page 7 of 8                 |       |

Wbc\_Offset, Lym\_Coeff, Lym\_Offset, Cd4\_Coeff, Cd4\_Offset, respectively) or FCS file (PCTWBCCoeff, PCTWBCOffset, PCTL YM Coeff, PCTL YMOffset, PCTCD4Coeff, PCTCD4Offset, respectively).

- 6.2.1. When called by the AuRICA application WBC and Lymphocyte values shall be rounded to the nearest 100.
- 6.2.2. A setting in the initialization file (ReportMode) or FCS file (PCTReportMode) shall permit reporting of the uncalibrated result.
- 6.2.3. A setting in the initialization file (Silent) shall permit reporting of the unrounded WBC and Lymphocyte values in off-line analysis mode.

## 7. Flag Generation

- 7.1. The following error conditions shall be detected and reported in the results file via a single ASCII character.
- 7.2. Flags shall be checked and reported in the following order where the most serious condition is listed first and only the most serious flag is reported.
  - 7.2.1. An "X" shall indicate that the FCS data file supplied could not be read or properly parsed and that no data values are trustworthy.
  - 7.2.2. A "T" shall indicate that the machine event count limit as defined in the initialization file (Max\_Events) or FCS file (PCTMaxEvents) was exceeded and that one of the following is also true: a) the percentage of these events that were digitized fell below 10%, or b) less than 500 of these digitized events were identified as CD4-positive.
  - 7.2.3. A "W" shall indicate that less than 1000 WBC counts were identified and that no data values are trustworthy.
  - 7.2.4. A "U" shall indicate that the lymphocyte cluster centroid could not be reliably located and that no data values are trustworthy.
    - 7.2.4.1. A center stability setting in the initialization file (Center\_Stability ) or in the FCS file (PCTCenterStability) shall determine an acceptable amount of variability allowed in the lymphocyte cluster centroid X and Y coordinates.
  - 7.2.5. An "L" shall indicate that the lymphocyte centroid was abnormally low or that the data was abnormally distributed in the TOF/FSH plot and that no data values are trustworthy.

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| Effective Date:<br>3/3/2006  | PointCare Algorithm and Flag Requirements<br>Specification | Page 8 of 8                 |       |

7.2.6. A "D" shall indicate that a gross anomaly was detected in the sample flow rate and that no data values are trustworthy.

7.2.7. A "Z" flag shall indicate that the angle search returned a value less than zero and that the separation angle could not be reliably located and that no data values are trustworthy.

END OF DOCUMENT

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| Effective Date:<br>8/24/2006   | SEQUENCE REQUIREMENTS SPECIFICATION | Page 1 of 39                |       |

| Rev | ECO    | Date      | Description                  |
|-----|--------|-----------|------------------------------|
| A   | E-0060 | 3/14/2005 | Initial Release              |
| B   | E-0191 | 2/28/2006 | Updates for New Lyse Project |
| C   | E-0245 | 3/21/2006 | Updates for revision 2.2.1   |
| D   | E-0310 | 7/18/2006 | Updates or revision 2.2.6    |
| E   | E-0326 | 8/17/2006 | Updates for revision 2.2.7   |
| F   | E-0341 | 8/24/2006 | Updates for revision 2.2.8   |

| Name               | Signature | Date | Title                    | Approval Function |
|--------------------|-----------|------|--------------------------|-------------------|
| Jennifer Waite     |           |      | Software Engineer        | Originator        |
| Andrea Desrosiers  |           |      | Software Manager         | Technical Review  |
| Don Barry          |           |      | Scientist                | Technical Review  |
| Kassey Kalukiewicz |           |      | Chief Operations Officer | Technical Review  |
| Maurice Doire      |           |      | Quality Assurance        | QA and QC         |

ORIGINATOR Jennifer Waite

TITLE: SEQUENCE REQUIREMENTS SPECIFICATION

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 2 of 39                   |        |

## 1. Introduction

This document describes requirements for the Point Care Technologies AurICA System Software sequences. The sequence is the part of the software that controls the optical, fluidic and data acquisition subsystems.

## 2. Scope

This document shall provide software requirements in enough depth to permit the construction of test cases that address all sequence software functions.

2.1. This document applies to software revision 2.2.8 which consists of the following changes to the last formally released revision 2.2.7.

- 2.1.1. Added the Extended Startup Sequence which performs the same fluidic movements as the Startup After Shipment Sequence.
- 2.1.2. Added the "Extended Startup Idle Time" and "Do Extended Startup" service parameters.
- 2.1.3. Added message to the beginning of the Run Patient sequence reminding the operator that blood samples must be analyzed within 10 hours of collection.

## 3. Applicable Documentation

- SRS-002 Software Requirements Specification
- SRS-003 System Hazard Analysis
- SRS-006 Algorithm Specification
- NL-0018 Software Status Report

## 4. Sequence Requirements

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 3 of 39                   |        |

## 4.1. Sample Run

### 4.1.1. Barcode Sequence

- 4.1.1.1. The barcodes shall be read on the tubes in this order: Slot 4 (Lyse), Slot 3 (Quench), Slot 2 (Consumable), Slot 1 (if Patient Sample or CD4 Control Material).
- 4.1.1.2. For each tube, the spinner shall come down and spin the tube while the barcode reader reads the barcode string from the label on the tube.
- 4.1.1.3. The vial shall not move the next tube under the spinner unless the barcode string read for that slot is of the format specified in Appendix E.
- 4.1.1.4. If the barcode reader is unable to read the barcode string, it shall try to read the barcode 4 more times.
- 4.1.1.5. If the barcode reader is unable to read the barcode string on the tube after 5 tries, the user shall be alerted and the sequence shall be aborted.

### 4.1.2. Sanity Checks

- 4.1.2.1. The user shall be prompted to mix the patient or control sample tube before the sequence can proceed.
- 4.1.2.2. The user shall be reminded that blood samples must be analyzed within 10 hours of collection before the sequence can proceed.
- 4.1.2.3. Before any dilutions are made, the temperature of the heater block is checked to make sure it falls within the allowable range (37°C - 39°C).
- 4.1.2.4. If the temperature doesn't fall within the allowable range, the user shall be asked if he/she wants to abort the sequence or wait until the temperature becomes within range.
- 4.1.2.5. The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.
- 4.1.2.6. The fluid level on the sheath bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the sheath bottle before the sequence can continue.
- 4.1.2.7. The vial block lid sensor shall be checked to see if the lid is open. If the lid is open, the user shall be prompted to close the lid before the sequence can continue.

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 4 of 39                   |        |

4.1.2.8. The instrument cover sensor shall be checked to see if the cover has been taken off. If the cover is off, the user shall be prompted to replace the cover before the sequence can continue.

#### 4.1.3. Making the Blood Dilution

4.1.3.1. The consumable tube shall be vented before any fluid is added to the tube.

4.1.3.2. If barcode checking is enabled, the Lyse tube shall be vented if it is a fresh tube (on its first use). If barcode checking is disabled, the Lyse tube shall be vented on every sample.

4.1.3.3. The mixer shall be lowered to an appropriate height to mix the blood or QC material tube.

4.1.3.4. A 15µl air gap is aspirated by the probe to provide a space between sheath and sample material.

4.1.3.5. The probe shall be lowered to an appropriate height to get a baseline capacitance reading before searching for the meniscus of the blood or QC material tube.

4.1.3.6. A set amount (service parameter) of material shall be aspirated from the meniscus of the sample tube.

4.1.3.7. If the meniscus of the sample material cannot be found, the user shall be alerted and the sequence shall abort.

4.1.3.8. If the sequence aborts during the dilution, the lines shall be flushed to get rid of any air and the system shall reset to bring all components back to the home position.

4.1.3.9. The system shall dispense the sample material along with the 15µl of air and a set amount (service parameter) of sheath at the bottom of the consumable tube.

4.1.3.10. The consumable tube shall then be spun back and forth at a set speed and duration (service parameters).

4.1.3.11. The consumable tube shall be left to incubate for a set duration (service parameter).

4.1.3.12. The consumable tube shall be spun back and forth at a set speed and duration (service parameters) at specified intervals (service parameter) during the incubation period.

#### 4.1.4. Lysing

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 5 of 39                   |        |

- 4.1.4.1. If the sum of the service parameters for Reagent B Volume, Air Volume, and Reagent A Volume exceeds the instrument's total path length, then an error message will be presented and the sequence will abort.
- 4.1.4.2. 635µl of sheath is loaded by the diluent syringe for the purpose of "charging" the fluid capacitor.
- 4.1.4.3. 635µl of sheath is dispensed into the fluid capacitor to "charge" it.
- 4.1.4.4. A set volume (service parameter) of Reagent C (sheath) is loaded by the diluent syringe.
- 4.1.4.5. A set volume (service parameter) of air is aspirated by the probe to provide a space between Reagent C and Reagent B.
- 4.1.4.6. A set volume (service parameter) of Reagent B shall be aspirated from the meniscus of the Quench Tube in the 3rd position of the vial.
- 4.1.4.7. The probes shall be lowered to the bottom of the Quench Tube and raised back to home to briefly rinse the vent hole.
- 4.1.4.8. A set volume (service parameter) of air is aspirated by the probe to provide a space between Reagent B and Reagent A.
- 4.1.4.9. A set volume (service parameter) of Reagent A shall be aspirated from the meniscus of the Lyse Tube in the 4th position of the vial.
- 4.1.4.10. If the meniscus of Reagent A or Reagent B cannot be found, the user shall be alerted and the sequence shall abort.
- 4.1.4.11. If the sequence aborts during the lysing, the lines shall be flushed to get rid of any air and the system shall reset to bring all components back to the home position. All waste will be dispensed back into the consumable tube.
- 4.1.4.12. The system shall dispense Reagent A at the bottom of the consumable tube at a set speed (service parameter).
- 4.1.4.13. The system shall dispense the air bubble at the bottom of the consumable tube at a set speed (service parameter).
- 4.1.4.14. If enabled (service parameter) the probe will aspirate and dispense a volume (service parameter) of fluid from the consumable tube at a set speed (service parameter) and will repeat the aspiration/dispensing a set number of times (service parameter).

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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 6 of 39                   |        |

4.1.4.15.The system shall wait a set number (service parameter) of seconds before dispensing Reagent B.

4.1.4.16.The system shall dispense Reagent B at the bottom of the consumable tube at a set speed (service parameter).

4.1.4.17.The system shall dispense the second air bubble at the bottom of the consumable tube at a set speed (service parameter).

4.1.4.18.The system shall dispense Reagent C at the bottom of the consumable tube at a set speed (service parameter).

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|--|--|--------------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 7 of 39                   |        |

#### 4.1.5. Sample Aspiration and Data Acquisition

4.1.5.1. Prior to sample aspiration, the diluent syringe and the sample syringe shall be filled to close to their capacity with sheath.

4.1.5.2. The consumable tube shall be spun by the mixer.

4.1.5.3. A 60 $\mu$ l air gap is aspirated by the probe to provide a space between sheath and the diluted sample.

4.1.5.4. 210 $\mu$ l of diluted sample shall be aspirated from 200 steps above the bottom of the consumable tube.

4.1.5.5. The sample shall then be moved into the Manifold Block so it can be analyzed by the HGB sensors

4.1.5.6. The diluent syringe shall then start dispensing at a constant rate through the flowcell during the data acquisition

4.1.5.7. The sample syringe shall boost the sample quickly to the flowcell and then dispense slowly during the data acquisition

4.1.5.8. Laser data shall be acquired on the sample at a set rate (service parameter) for a set duration (service parameter)

4.1.5.9. The system shall dispense all leftover waste material back into the consumable tube

4.1.5.10. The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.

4.1.5.11. The fluid level on the sheath bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the sheath bottle before the sequence can continue.

4.1.5.12. The system shall do a total flush and reset (return all instrument components to home position) to ready the instrument for the next sample.

|  |  |                                |        |
|--|--|--------------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 8 of 39                   |        |

## 4.2. Startup

### 4.2.1. System Setup

- 4.2.1.1. The heater shall be enabled
- 4.2.1.2. The heater low temperature shall be set to 37°C
- 4.2.1.3. The heater high temperature shall be set to 38°C
- 4.2.1.4. The temperature controller shall be started
- 4.2.1.5. The Instrument's real time clock shall be set to the PC's current time

### 4.2.2. Sanity Checks

- 4.2.2.1. The user shall be prompted to insert the sheath reagent bottle
- 4.2.2.2. The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.
- 4.2.2.3. The fluid level on the sheath bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the sheath bottle before the sequence can continue.
- 4.2.2.4. The vial block lid sensor shall be checked to see if the lid is open. If the lid is open, the user shall be prompted to close the lid before the sequence can continue.
- 4.2.2.5. The instrument cover sensor shall be checked to see if the cover has been taken off. If the cover is off, the user shall be prompted to replace the cover before the sequence can continue.

### 4.2.3. Barcode Checking

- 4.2.3.1. The only barcode that shall be read is on the Waste tube in Slot 3. There are no other tubes present during Startup.
- 4.2.3.2. The spinner shall come down and spin the tube while the barcode reader reads the barcode string from the label on the tube.
- 4.2.3.3. The sequence shall not continue unless the barcode string read for Slot 3 is of the format specified in Appendix E.
- 4.2.3.4. If the barcode reader is unable to read the barcode string, it shall try to read the barcode 4 more times.

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|--|--|--------------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 9 of 39                   |        |

4.2.3.5. If the barcode reader is unable to read the barcode string on the tube after 5 tries, the user shall be alerted and the sequence shall be aborted.

#### 4.2.4. Startup Cycle

4.2.4.1. The system shall cycle 9mL of sheath through the flowcell using the diluent syringe.

4.2.4.2. The system shall push 2mL of sheath through the probe.

4.2.4.3. The system shall perform 1 prime cycle (see 4.4.1).

4.2.4.4. The probes shall be lowered to the bottom of the Waste Tube and raised back to home to briefly rinse the vent hole.

4.2.4.5. The system shall return all instrument components to the home position.

### 4.3. Prime

#### 4.3.1. Prime Cycle

4.3.1.1. The system shall push 2mL of sheath through the probe into the Waste Tube.

4.3.1.2. The system shall push 2.5mL of sheath through both paths of the flowcell at once.

4.3.1.3. The system shall push 475µl of sheath into the fluid capacitor to "charge" it.

4.3.1.4. The system shall pull 20µl with the Diluent Syringe while valves F, E, and B are open (fluid capacitor is discharging into the flowcell at the same time). This will help get rid of air bubbles in the flowcell.

4.3.1.5. The system will push 150µl (home the diluent syringe) through both paths of the flowcell at once.

4.3.1.6. The system shall return all instrument components to the home position.

### 4.4. Clean

#### 4.4.1. Sanity Checks

4.4.1.1. The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.

4.4.1.2. The fluid level on the sheath bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the sheath bottle before the sequence can continue.

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|--|--|--------------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 10 of 39                  |        |

4.4.1.3. The vial block lid sensor shall be checked to see if the lid is open. If the lid is open, the user shall be prompted to close the lid before the sequence can continue.

4.4.1.4. The instrument cover sensor shall be checked to see if the cover has been taken off. If the cover is off, the user shall be prompted to replace the cover before the sequence can continue.

#### 4.4.2. Barcode Checking

4.4.2.1. The barcodes shall be read on the tubes in this order: Slot 4 (Cleaner), Slot 3 (Waste). There are no other tubes present during a Clean Sequence.

4.4.2.2. For each tube, the spinner shall come down and spin the tube while the barcode reader reads the barcode string from the label on the tube.

4.4.2.3. The vial shall not move the next tube under the spinner unless the barcode string read for that slot is of the format specified in Appendix E.

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|--|--|--------------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 11 of 39                  |        |

4.4.2.4. If the barcode reader is unable to read the barcode string, it shall try to read the barcode 4 more times.

4.4.2.5. If the barcode reader is unable to read the barcode string on the tube after 5 tries, the user shall be alerted and the sequence shall be aborted.

#### 4.4.3. Clean Cycle

4.4.3.1. The vent needle shall be cleaned by moving the probes into the Clean Tube (far enough so the vent hole is emerged) and aspirating and dispensing cleaner fluid with the sample probe. This will push and pull cleaner fluid into and out of the vent probe.

4.4.3.2. To make sure no fluid is left in the vent probe, the probes shall be moved into the air above the liquid in the Clean Tube and air shall be aspirated and dispensed by the sample probe. This will force air into and out of the vent probe.

4.4.3.3. A 60µl air gap shall be aspirated by the probe to provide a space between sheath and cleaner fluid.

4.4.3.4. The Clean Tube in slot 4 shall be spun by the mixer.

4.4.3.5. 600µl of cleaner fluid shall be aspirated from the meniscus of the Clean Tube.

4.4.3.6. If 600µl cleaner fluid + 60µl air exceeds the instrument's total path length, then the volume of cleaner fluid aspirated will be decreased so that it is under the total path length volume

4.4.3.7. If the meniscus of the cleaner fluid cannot be found, the user shall be alerted and the sequence shall abort.

4.4.3.8. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the manifold block and the probe.

4.4.3.9. 100µl of cleaner fluid shall be dispensed through the sample path of the flowcell

4.4.3.10. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell

4.4.3.11. During the soak period, the probes shall rest on the bottom of the Cleaning Tube so that the vent hole is soaked.

|  |  |                             |        |
|--|--|-----------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 12 of 39               |        |

4.4.3.12. 100µl more cleaner fluid shall be dispensed through the sample path of the flowcell

4.4.3.13. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell

4.4.3.14. During the soak period, the probes shall rest on the bottom of the Cleaning Tube so that the vent hole is soaked.

4.4.3.15. 800µl of sheath shall be flushed through the manifold and the probe into the Waste Tube.

4.4.3.16. The system shall perform 2 prime cycles (see 4.4.1) to rinse out the rest of the cleaner fluid from the system.

## 4.5. Shutdown

### 4.5.1. Sanity Checks

4.5.1.1. The user shall be prompted to insert the Shutdown Solution bottle.

4.5.1.2. The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.

4.5.1.3. The fluid level on the Shutdown Solution bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the Shutdown Solution bottle before the sequence can continue.

4.5.1.4. The vial block lid sensor shall be checked to see if the lid is open. If the lid is open, the user shall be prompted to close the lid before the sequence can continue.

4.5.1.5. The instrument cover sensor shall be checked to see if the cover has been taken off. If the cover is off, the user shall be prompted to replace the cover before the sequence can continue.

### 4.5.2. Barcode Checking

4.5.2.1. The barcodes shall be read on the tubes in this order: Slot 4 (Cleaner), Slot 3 (Waste). There are no other tubes present during a Shutdown Sequence.

4.5.2.2. For each tube, the spinner shall come down and spin the tube while the barcode reader reads the barcode string from the label on the tube.

4.5.2.3. The vial shall not move the next tube under the spinner unless the barcode string read for that slot is of the format specified in Appendix E. If the barcode reader is unable to read the barcode string, it shall try to read the barcode 4 more times.

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|--|--|--------------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 13 of 39                  |        |

4.5.2.4. If the barcode reader is unable to read the barcode string on the tube after 5 tries, the user shall be alerted and the sequence shall be aborted.

#### 4.5.3. Shutdown Cycle

4.5.3.1. A 60µl air gap shall be aspirated by the probe to provide a space between sheath and cleaner fluid.

4.5.3.2. The Clean Tube in slot 4 shall be spun with the mixer.

4.5.3.3. 600µl of cleaner fluid shall be aspirated from the meniscus of the Clean Tube.

4.5.3.4. If 600µl cleaner fluid + 60µl air exceeds the instrument's total path length, then the volume of cleaner fluid aspirated will be decreased so that it is under the total path length volume

4.5.3.5. If the meniscus of the cleaner fluid cannot be found, the user shall be alerted and the sequence shall abort.

4.5.3.6. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the manifold block and the probe.

4.5.3.7. 100µl of cleaner fluid shall be dispensed through the sample path of the flowcell

4.5.3.8. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell.

4.5.3.9. The fluid in the flowcell shall be agitated by pushing and pulling 20µl with the diluent syringe.

4.5.3.10. The fluid in the manifold block shall be agitated by pushing and pulling 20µl with the diluent syringe.

4.5.3.11. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell.

4.5.3.12. The fluid in the manifold block shall be agitated by pushing and pulling 20µl with the diluent syringe.

4.5.3.13. 100µl more cleaner fluid shall be dispensed through the sample path of the flowcell

4.5.3.14. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell.

4.5.3.15. The fluid in the flowcell shall be agitated by pushing and pulling 20µl with the diluent syringe.

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|--|--|--------------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 14 of 39                  |        |

4.5.3.16.The fluid in the manifold block shall be agitated by pushing and pulling 20µl with the diluent syringe.

4.5.3.17.The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell.

4.5.3.18.During the four soak periods, the probes shall rest on the bottom of the Cleaning Tube so that the vent hole is soaked.

4.5.3.19.800µl of Shutdown Solution shall be flushed through the manifold and the probe into the Waste Tube.

4.5.3.20.The vent needle shall be rinsed by moving the probes into the Clean Tube (far enough so the vent hole is emerged) and aspirating and dispensing cleaner fluid with the sample probe. This will push and pull cleaner fluid into and out of the vent probe.

4.5.3.21.To make sure no fluid is left in the vent probe, the probes shall be moved into the air above the liquid in the Clean Tube and air shall be aspirated and dispensed by the sample probe. This will force air into and out of the vent probe.

4.5.3.22.The system shall then perform 2 prime cycles (see 4.4.1).

4.5.3.23.After each prime, as a safeguard, the Waste Tube shall be checked to see if it has been overfilled and if so, the operator shall be notified.

4.5.3.23.1.If the Waste Tube is full, the operator shall have a chance to insert a new Waste Tube and continue with the Shutdown Cycle.

4.5.3.24.The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.

4.5.3.25.The fluid level on the Shutdown Solution bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the Shutdown Solution bottle before the sequence can continue.

|  |  |                                |        |
|--|--|--------------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 15 of 39                  |        |

4.5.3.26. The system shall push 1mL of Shutdown solution through the probe into the Waste Tube.

4.5.3.27. The system shall cycle 18mL of Shutdown solution through the flowcell using the diluent syringe.

4.5.3.28. If end-of-day shutdown cycle is being performed, the probe shall be lowered to the bottom of the Clean Tube and 50µl of cleaning solution shall be aspirated.

4.5.3.29. If end-of-day shutdown cycle is being performed, the probe shall be left to soak at the bottom of the Clean Tube. Otherwise, the system shall return all instrument components to the home position.

#### 4.6. Shutdown for Shipment

##### 4.6.1. Sanity Checks

4.6.1.1. The vial block lid sensor shall be checked to see if the lid is open. If the lid is open, the user shall be prompted to close the lid before the sequence can continue.

4.6.1.2. The instrument cover sensor shall be checked to see if the cover has been taken off. If the cover is off, the user shall be prompted to replace the cover before the sequence can continue.

4.6.1.3. The user shall be prompted to replace the sheath bottle with the Shutdown Solution bottle

4.6.1.4. The fluid level on the Shutdown Solution bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the Shutdown Solution bottle before the sequence can continue.

4.6.1.5. The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.

4.6.1.6. The user shall be prompted to insert a waste tube into position three of the vial block.

##### 4.6.2. Barcode Checking

4.6.2.1. The only barcode that shall be read is on the Waste tube in Slot 3. There are no other tubes present during a Shutdown For Shipment.

4.6.2.2. The spinner shall come down and spin the tube while the barcode reader reads the barcode string from the label on the tube.

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**EXHIBIT 3 - 2**

|  |  |                             |        |
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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 16 of 39               |        |

4.6.2.3. The sequence shall not continue unless the barcode string read for Slot 3 is of the format specified in Appendix E. If the barcode reader is unable to read the barcode string, it shall try to read the barcode 4 more times.

4.6.2.4. If the barcode reader is unable to read the barcode string on the tube after 5 tries, the user shall be alerted and the sequence shall be aborted.

#### 4.6.3. Shutdown for Shipment Cycle

4.6.3.1. The system shall then perform 1 prime cycle (see 4.4.1).

4.6.3.2. The user shall be prompted to remove the cap from the Shutdown Solution bottle so that the probes are in the air.

4.6.3.3. The fluid level on the Shutdown Solution bottle shall be checked to make sure it is empty. If it is not empty, the user shall be prompted to remove the cap from the Shutdown Solution bottle so that the probes are in the air.

4.6.3.4. The system shall then perform 1 prime cycle (see 4.4.1).

4.6.3.5. The user shall be prompted to remove the used system filter beneath the bottle tray and install a new filter.

4.6.3.6. The user shall be prompted to remove all the tubes from the vial rack.

4.6.3.7. The spinner and the barcode reader shall be used to verify that there are no tubes left in the vial rack.

4.6.3.8. The user shall be prompted to replace the Waste and Shutdown Solution bottles with dry bottles.

4.6.3.9. The fluid level on the Shutdown Solution bottle shall be checked to make sure it is empty. If it is not empty, the user shall be prompted to replace the Shutdown Solution bottle with a dry bottle.

4.6.3.10. The fluid level on the waste bottle shall be checked to make sure it is not full. If it is full, the user shall be prompted to replace the Waste bottle with a dry bottle.

4.6.3.11. The user shall be notified that the Shutdown Cycle is complete before the software exits.

#### 4.7. Startup After Shipment/Extended Startup

##### 4.7.1. System Setup

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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 17 of 39                  |        |

4.7.1.1. The heater shall be enabled

4.7.1.2. The heater low temperature shall be set to 37°C

4.7.1.3. The heater high temperature shall be set to 38°C

4.7.1.4. The temperature controller shall be started

4.7.1.5. The Instrument's real time clock shall be set to the PC's current time

#### 4.7.2. Sanity Checks

4.7.2.1. The user shall be prompted to insert the sheath reagent bottle

4.7.2.2. The user shall be prompted to insert the Waste bottle containing a disinfectant tablet only if a Startup After Shipment is being run.

4.7.2.3. The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.

4.7.2.4. The fluid level on the sheath bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the sheath bottle before the sequence can continue.

4.7.2.5. The vial block lid sensor shall be checked to see if the lid is open. If the lid is open, the user shall be prompted to close the lid before the sequence can continue.

4.7.2.6. The instrument cover sensor shall be checked to see if the cover has been taken off. If the cover is off, the user shall be prompted to replace the cover before the sequence can continue.

#### 4.7.3. Barcode Checking

4.7.3.1. The barcodes shall be read on the tubes in this order: Slot 4 (Cleaner), Slot 3 (Waste). There are no other tubes present during a Shutdown Sequence.

4.7.3.2. For each tube, the spinner shall come down and spin the tube while the barcode reader reads the barcode string from the label on the tube.

4.7.3.3. The vial shall not move the next tube under the spinner unless the barcode string read for that slot is of the specified in Appendix E..

4.7.3.4. If the barcode reader is unable to read the barcode string, it shall try to read the barcode 4 more times.

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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 18 of 39               |        |

4.7.3.5. If the barcode reader is unable to read the barcode string on the tube after 5 tries, the user shall be alerted and the sequence shall be aborted.

#### 4.7.4. Startup After Shipment/Extended Startup Cycle

4.7.4.1. The system shall perform 2 prime cycles (see 4.4.1).

4.7.4.2. After each prime, as a safeguard, the Waste Tube shall be checked to see if it has been overfilled and if so, the operator shall be notified.

4.7.4.2.1. If the Waste Tube is full, the operator shall have a chance to insert a new Waste Tube and continue with the Shutdown Cycle.

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|--|--|-----------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 19 of 39               |        |

- 4.7.4.3. A 60 $\mu$ l air gap shall be aspirated by the probe to provide a space between sheath and cleaner fluid.
- 4.7.4.4. The Clean Tube in slot 4 shall be spun by the mixer.
- 4.7.4.5. 600 $\mu$ l of cleaner fluid shall be aspirated from the meniscus of the Clean Tube.
- 4.7.4.6. If 600 $\mu$ l cleaner fluid + 60 $\mu$ l air exceeds the instrument's total path length, then the volume of cleaner fluid aspirated will be decreased so that it is under the total path length volume
- 4.7.4.7. If the meniscus of the cleaner fluid cannot be found, the user shall be alerted and the sequence shall abort.
- 4.7.4.8. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the manifold block and the probe.
- 4.7.4.9. 100 $\mu$ l of cleaner fluid shall be dispensed through the sample path of the flowcell
- 4.7.4.10. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell.
- 4.7.4.11. The fluid in the flowcell shall be agitated by pushing and pulling 20 $\mu$ l with the diluent syringe.
- 4.7.4.12. The fluid in the manifold block shall be agitated by pushing and pulling 20 $\mu$ l with the diluent syringe.
- 4.7.4.13. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell.
- 4.7.4.14. The fluid in the manifold block shall be agitated by pushing and pulling 20 $\mu$ l with the diluent syringe.
- 4.7.4.15. 100 $\mu$ l more cleaner fluid shall be dispensed through the sample path of the flowcell
- 4.7.4.16. The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell.
- 4.7.4.17. The fluid in the flowcell shall be agitated by pushing and pulling 20 $\mu$ l with the diluent syringe.
- 4.7.4.18. The fluid in the manifold block shall be agitated by pushing and pulling 20 $\mu$ l with the diluent syringe.

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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 20 of 39                  |        |

4.7.4.19.The system shall wait for a set amount of time (service parameter) to allow the cleaner fluid to soak in the flowcell.

4.7.4.20.During the four soak periods, the vent needle shall be cleaned. See sections 4.5.3.1 and 4.5.3.2.

4.7.4.21.During the four soak periods, after the vent clean, the probes shall rest on the bottom of the Cleaning Tube so that the vent hole is soaked.

4.7.4.22.800µl of sheath shall be flushed through the manifold and the probe into the Waste Tube.

4.7.4.23.The system shall then perform 2 prime cycles (see 4.4.1).

4.7.4.24.After each prime, as a safeguard, the Waste Tube shall be checked to see if it has been overfilled and if so, the operator shall be notified.

4.7.4.24.1.If the Waste Tube is full, the operator shall have a chance to insert a new Waste Tube and continue with the Shutdown Cycle.

4.7.4.25.The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.

4.7.4.26.The fluid level on the sheath bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the sheath bottle before the sequence can continue.

4.7.4.27.The system shall cycle 18mL of sheath through the flowcell using the diluent syringe.

4.7.4.28.The system shall return all instrument components to the home position.

|  |  |                             |        |
|--|--|-----------------------------|--------|
|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document Number:<br>SRS 005 | Rev. F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 21 of 39               |        |

## 4.8. Automatic Maintenance

### 4.8.1. Sanity Checks

- 4.8.1.1. The fluid level on the waste bottle shall be checked to see if it is full. If it is full, the user shall be prompted to empty the waste bottle before the sequence can continue.
- 4.8.1.2. The fluid level on the sheath bottle shall be checked to see if it is empty. If it is empty, the user shall be prompted to replace the sheath bottle before the sequence can continue.
- 4.8.1.3. The instrument cover sensor shall be checked to see if the cover has been taken off. If the cover is off, the user shall be prompted to replace the cover before the sequence can continue.

### 4.8.2. Automatic Maintenance Cycle

- 4.8.2.1. The system shall load 50µl of sheath with the diluent syringe
- 4.8.2.2. The system shall push 50µl of sheath with the diluent syringe into sheath path of flowcell
- 4.8.2.3. The system shall load 50µl of sheath with the sample syringe
- 4.8.2.4. The system shall push 50µl of sheath with the sample syringe into sample path of flowcell
- 4.8.2.5. The system shall open valve C and close it to make sure it's exercised
- 4.8.2.6. If it is sensed that the vial block lid is closed, the vial shall be moved so that the 3rd position of the vial is under the probes.
- 4.8.2.7. The probes shall be lowered down to the bottom of the block and then raised back up to briefly rinse the vent hole if the Waste or Quench Tube happens to be in the 3rd position when this sequence is executed.
- 4.8.2.8. The system shall return all instrument components to their home position.

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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 22 of 39               |        |

## Appendix A: Service Parameter List

| Name                             | Default Value | Units  | Description   |
|----------------------------------|---------------|--|---|
| Simulated Mode                   | 0             | 0 off, 1 random, 2 analysis, 3 import                  | 0=no simulation, 1=random results, 2=analyze test.fcs file, 3=import results from results.txt file  |
| Startup Mode                     | 1             | 1 with prime, 0 no prime                               | 1=run full startup cycle, 0=only turn on heater but don't move any fluid  |
| Development Mode                 | 0             | 1 dev mode, 0 customer mode                            | 1=show verbose status messages during cycle   |
| Check Barcodes                   | 1             | 1 on, 0 off  |   |
| Check Bottles                    | 7             | 0 off, 1 ss, 2 w, 3 w+ss, 4 s, 5 s+ss, 6 s+w, 7 s+w+ss | 0=no bottle checking, 1=check shutdown solution only, 2=check waste only, 3=check waste and shutdown solution, 4=check sheath only, 5=check sheath and shutdown solution, 6=check sheath and waste, 7=check all bottles |
| Locale                           | 1             | 0 domestic, 1 international                            | 0=abort test on expired tubes and show "for research only" on all screens   |
| Heater Mode                      | 1             | 1 heater on, 0 heater off                              |   |
| Incubation Time                  | 240           | seconds  | incubation time after 1st dilution of patient test  |
| Sample Volume                    | 25            | µl   | volume of blood to use in 1st dilution of patient test  |
| Sheath Volume                    | 25            | µl   | volume of sheath to use in 1st dilution of patient test   |
| CD4 Control Incubation Time      | 900           | seconds  | incubation time after 1st dilution of CD4 control test  |
| CD4 Control Sample Volume        | 25            | µl   | volume of control material to use in 1st dilution of CD4 control test   |
| CD4 Control Sheath Volume        | 25            | µl   | volume of sheath to use in 1st dilution of CD4 control test   |
| External Control Incubation Time | 0             | seconds  | incubation time after 1st dilution of External control test   |
| External Control Sample Volume   | 25            | µl   | volume of control material to use in 1st dilution of External control test  |

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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 23 of 39               |        |

|                                |       |  |   |
|--------------------------------|-------|--|---|
| External Control Sheath Volume | 25    | µl   | volume of sheath to use in 1st dilution of External control test                              |
| Volume A                       | 400   | µl   | Lyse Reagent A  |
| Volume B                       | 300   | µl   | Lyse Reagent B  |
| Volume C                       | 0     | µl   | Lyse Reagent C (sheath)   |
| Dispense A Speed               | 200   | 1-600 (keep FAR away from the extremities)         | speed of dispensing Reagent A   |
| Dispense B Speed               | 300   | 1-600 (keep FAR away from the extremities)         | speed of dispensing Reagent B   |
| Dispense C Speed               | 550   | 1-600 (keep FAR away from the extremities)         | speed of dispensing Reagent C   |
| Air 1 Volume                   | 75    | µl (bubble between C & B)                          | volume of air gap between Reagent C & B   |
| Air 1 Speed                    | 200   | 1-600 (keep FAR away from the extremities)         | speed of dispensing air gap 1   |
| Air 2 Volume                   | 75    | µl (bubble between B & A)                          | volume of air gap between Reagent B & A   |
| Air 2 Speed                    | 200   | 1-600 (keep FAR away from the extremities)         | speed of dispensing air gap 2   |
| Wait Time                      | 0     | seconds to wait after dispensing A and air         |   |
| Do Mix                         | 0     | 1 mix (with probe only) during A dispense, 0 don't | after dispensing Reagent A, do mix by aspirating and dispensing fluid with probe              |
| Probe Mix Speed                | 550   | 1-600 (keep FAR away from the extremities)         | speed to aspirate and dispense during probe mix   |
| Probe Mix Volume               | 250   | µl   | volume and aspirate and dispense during probe mix   |
| Probe Mix Repeat               | 2     | number of times to aspirate/dispense with probe    |   |
| Analyze Time                   | 35000 | milliseconds                                       | amount of time to acquire laser data  |
| Sample Rate                    | 0.76  | µl/s   | Speed of syringe during data acquisition ("WBCSampleRate" parameter from instrument database) |
| Fifo Time                      | 300   | milliseconds                                       | Time between Fifo reads during data acquisition   |
| Gold Mix Speed                 | 150   | 1 - 499  | Speed at which to spin gold tube after 1st dilution of a patient test                         |
| Gold Mix Forward Time          | 5     | tenths of seconds                                  | duration for forward spin   |
| Gold Mix Reverse Time          | 5     | tenths of seconds                                  | duration of backward spin   |
| Gold Mix Repeat                | 60    | number of times to do forward/backward motion      |   |

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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 24 of 39               |        |

|  |     |   |   |
|--|-----|---|---|
| Gold Mix Interval                      | 60  | seconds (mix every x seconds during incubation) | do mix using "Gold Mix" parameters at specified interval during incubation                  |
| CD4 Control Gold Mix Speed             | 150 | 1 - 499   | Speed at which to spin gold tube after 1st dilution of a CD4 Control test                   |
| CD4 Control Gold Mix Forward Time      | 5   | tenths of seconds                               | duration for forward spin   |
| CD4 Control Gold Mix Reverse Time      | 5   | tenths of seconds                               | duration of backward spin   |
| CD4 Control Gold Mix Repeat            | 60  | number of times to do forward/backward motion   |   |
| CD4 Control Gold Mix Interval          | 60  | seconds (mix every x seconds during incubation) | do mix using "CD4 Control Gold Mix" parameters at specified interval during incubation      |
| External Control Gold Mix Speed        | 150 | 1 - 499   | Speed at which to spin gold tube after 1st dilution of an External Control test             |
| External Control Gold Mix Forward Time | 5   | tenths of seconds                               | duration for forward spin   |
| External Control Gold Mix Reverse Time | 5   | tenths of seconds                               | duration of backward spin   |
| External Control Gold Mix Repeat       | 60  | number of times to do forward/backward motion   |   |
| External Control Gold Mix Interval     | 60  | seconds (mix every x seconds during incubation) | do mix using "External Control Gold Mix" parameters at specified interval during incubation |
| Clean Cycle Run Count                  | 10  | number of tests                                 | number of tests before Clean cycle is enforced  |
| Clean Tube Run Count                   | 4   | number of tests                                 | number of tests before a new Clean Tube is required   |
| Lyse Tube Run Count                    | 10  | number of tests                                 | number of tests before a new Lyse Tube is required  |
| Quench Tube Run Count                  | 5   | number of tests                                 | number of tests before a new Quench Tube is required  |
| CD4 Control Tube Run Count             | 20  | number of tests                                 | number of tests before a new CD4 Control Tube is required.                                  |
| Heater High Temp                       | 38  | degrees C                                       |   |
| Heater Low Temp                        | 37  | degrees C                                       |   |

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 25 of 39                  |        |

|                                    |      |                                 |   |
|------------------------------------|------|---------------------------------|---|
| Max Temp                           | 39   | degrees C                       | maximum Heater High Temp value allowable  |
| Max Lyse Capacitance Threshold     | 100  | units of capacitance            | Threshold reading must be <= this number when finding lyse level  |
| Lyse Capacitance Threshold Delta   | 400  | units of capacitance            | reading in lyse must be >= threshold + this number  |
| Max Blood Capacitance Threshold    | 100  | units of capacitance            | Threshold reading must be <= this number when finding blood (or control material) level                                       |
| Blood Capacitance Threshold Delta  | 150  | units of capacitance            | reading in blood (or control material) must be >= threshold + this number   |
| Max Quench Capacitance Threshold   | 100  | units of capacitance            | Threshold reading must be <= this number when finding quench level  |
| Quench Capacitance Threshold Delta | 400  | units of capacitance            | reading in quench must be >= threshold + this number  |
| Force Shutdown                     | 1    | 1 enforced shutdown on, 0 off   | enforce shutdown before running any other cycle if instrument has been sitting idle for more than "Forced Shutdown Idle Time" |
| Forced Shutdown Idle Time          | 8    | hours                           | Run Automatic Exercise Cycle every "Exercise Cycle Idle Time" minutes   |
| Do Exercise Cycle                  | 1    | 1 do auto exercise cycle, 0 off |   |
| Exercise Cycle Idle Time           | 120  | minutes                         |   |
| Clean Needle Soak Time             | 135  | seconds                         | amount of time to soak needle and manifold during Clean Cycle   |
| Clean Flowcell Soak Time           | 40   | seconds (divided into 2 parts)  | amount of time to soak flowcell during Clean Cycle (divided into two chunks of time)  |
| Shutdown Needle Soak Time          | 135  | seconds                         | amount of time to soak needle and manifold during Shutdown and Startup After Shipment Cycles                                  |
| Shutdown Flowcell Soak Time        | 3600 | seconds (divided into 4 parts)  | amount of time to soak flowcell during Shutdown and Startup After Shipment Cycles (divided into four chunks of time)          |
| WBC Offset                         | 0    | counts                          | patient algorithm set up  |
| WBC Coefficient                    | 1.0  | decimal                         | patient algorithm set up  |
| LYM Offset                         | 0    | counts                          | patient algorithm set up  |

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 26 of 39                  |        |

|                             |       |  |  |
|-----------------------------|-------|--|--|
| LYM Coefficient             | 1.0   | decimal  | patient algorithm set up   |
| CD4 Offset                  | 0     | counts   | patient algorithm set up   |
| CD4 Coefficient             | 1.0   | decimal  | patient algorithm set up   |
| X Center Max                | 100   | bins   | patient algorithm set up   |
| X Center Min                | 60    | bins   | patient algorithm set up   |
| Y Center Max                | 55    | bins   | patient algorithm set up   |
| Y Center Min                | 10    | bins   | patient algorithm set up   |
| Lymph X Default             | 70    | bins   | patient algorithm set up   |
| Lymph Y Default             | 40    | bins   | patient algorithm set up   |
| Default Height              | 20    | bins   | patient algorithm set up   |
| Default Width               | 16    | bins   | patient algorithm set up   |
| FSL Thresh                  | 64    | bins   | patient algorithm set up   |
| FSH Thresh                  | 64    | bins   | patient algorithm set up   |
| Center Stability            | 0     | integer  | patient algorithm set up   |
| Max Events                  | 35000 | events   | patient algorithm set up   |
| CD4 Control Results Mode    | 1     | 0 cd4# only, 1 cd4N all, 2 cd4L all, 3 cd4N+cd4L all | 0=report CD4# only for both low and normal,<br>1=report all results for normal and only CD4# for<br>low, 2=report all results for low and only CD4# for<br>normal, 3=report all results for low and normal |
| CD4 Control WBC Offset      | 0     | counts   | CD4 control algorithm set up   |
| CD4 Control WBC Coefficient | 1.0   | decimal  | CD4 control algorithm set up   |
| CD4 Control LYM Offset      | 0     | counts   | CD4 control algorithm set up   |
| CD4 Control LYM Coefficient | 1.0   | decimal  | CD4 control algorithm set up   |
| CD4 Control CD4 Offset      | 0     | counts   | CD4 control algorithm set up   |
| CD4 Control CD4 Coefficient | 1.0   | decimal  | CD4 control algorithm set up   |
| CD4 Control X Center Max    | 75    | bins   | CD4 control algorithm set up   |
| CD4 Control X Center Min    | 45    | bins   | CD4 control algorithm set up   |
| CD4 Control Y Center Max    | 120   | bins   | CD4 control algorithm set up   |
| CD4 Control Y Center Min    | 0     | bins   | CD4 control algorithm set up   |
| CD4 Control Lymph X Default | 70    | bins   | CD4 control algorithm set up   |

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 27 of 39                  |        |

|                                   |       |                                     |   |
|-----------------------------------|-------|-------------------------------------|---|
| CD4 Control Lymph Y Default       | 60    | bins                                | CD4 control algorithm set up  |
| CD4 Control Default Height        | 18    | bins                                | CD4 control algorithm set up  |
| CD4 Control Default Width         | 16    | bins                                | CD4 control algorithm set up  |
| CD4 Control FSL Thresh            | 64    | bins                                | CD4 control algorithm set up  |
| CD4 Control FSH Thresh            | 64    | bins                                | CD4 control algorithm set up  |
| CD4 Control Center Stability      | 0     | integer                             | CD4 control algorithm set up  |
| CD4 Control Max Events            | 35000 | events                              | CD4 control algorithm set up  |
| External Control WBC Offset       | 0     | counts                              | External control algorithm set up   |
| External Control WBC Coefficient  | 1.0   | decimal                             | External control algorithm set up   |
| External Control LYM Offset       | 0     | counts                              | External control algorithm set up   |
| External Control LYM Coefficient  | 1.0   | decimal                             | External control algorithm set up   |
| External Control CD4 Offset       | 0     | counts                              | External control algorithm set up   |
| External Control CD4 Coefficient  | 1.0   | decimal                             | External control algorithm set up   |
| External Control X Center Max     | 75    | bins                                | External control algorithm set up   |
| External Control X Center Min     | 0     | bins                                | External control algorithm set up   |
| External Control Y Center Max     | 120   | bins                                | External control algorithm set up   |
| External Control Y Center Min     | 0     | bins                                | External control algorithm set up   |
| External Control Lymph X Default  | 70    | bins                                | External control algorithm set up   |
| External Control Lymph Y Default  | 60    | bins                                | External control algorithm set up   |
| External Control Default Height   | 18    | bins                                | External control algorithm set up   |
| External Control Default Width    | 16    | bins                                | External control algorithm set up   |
| External Control FSL Thresh       | 64    | bins                                | External control algorithm set up   |
| External Control FSH Thresh       | 64    | bins                                | External control algorithm set up   |
| External Control Center Stability | 0     | integer                             | External control algorithm set up   |
| External Control Max Events       | 35000 | events                              | External control algorithm set up   |
| Report Mode                       | 1     | 1 norm/calib results, 0 raw results | 1=report calibrated results, 0=report raw results   |
| Show Plots                        | 0     | 0 off 1 on (dev mode must = 1)      | 1=show dot plot during analysis, 0 = don't.<br>"Development Mode" must be 1 for this parameter to take affect |

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 28 of 39                  |        |

|                                   |      |                                |   |
|-----------------------------------|------|--------------------------------|---|
| Auto Print                        | 0    | 0 off 1 on (dev mode must = 1) | 1=auto print dot plot, 0 = don't. "Development Mode" and "Show Plots" must be 1 for this parameter to take affect |
| WBC Reportable Limit Low          | 1    | $10^3$ cells/ $\mu$ l          | reportable range low limit for WBC  |
| WBC Reportable Limit High         | 20   | $10^3$ cells/ $\mu$ l          | reportable range high limit for WBC   |
| LYM Reportable Limit Low          | 0.3  | $10^3$ cells/ $\mu$ l          | reportable range low limit for LYM  |
| LYM Reportable Limit High         | 6    | $10^3$ cells/ $\mu$ l          | reportable range high limit for LYM   |
| LYM Percent Reportable Limit Low  | 0.1  | percent                        | reportable range low limit for LYM%   |
| LYM Percent Reportable Limit High | 75   | percent                        | reportable range high limit for LYM%  |
| CD4 Reportable Limit Low          | 50   | cells/ $\mu$ l                 | reportable range low limit for CD4  |
| CD4 Reportable Limit High         | 3000 | cells/ $\mu$ l                 | reportable range high limit for CD4   |
| CD4 Percent Reportable Limit Low  | 0    | percent                        | reportable range low limit for CD4%   |
| CD4 Percent Reportable Limit High | 80   | percent                        | reportable range high limit for CD4%  |
| Needle Top Height                 | #    | half steps                     | "NeedleCal" parameter from instrument database  |
| Needle Bottom Height              | #    | half steps                     | "NeedleBottomHalfStepsFromHome" parameter from instrument database  |
| Path Length Volume                | #    | $\mu$ l                        | "PathLengthVol" parameter from instrument database  |
| Manifold To FlowCell Path Volume  | #    | $\mu$ l                        | "ManifoldFlowCellPathVol" parameter from instrument database  |
| FSH Peak Gain                     | #    | total gain                     | synced with instrument database gain settings   |
| FSL Peak Gain                     | #    | total gain                     | synced with instrument database gain settings   |
| RAS Peak Gain                     | #    | total gain                     | synced with instrument database gain settings   |
| EXT Peak Gain                     | #    | total gain                     | synced with instrument database gain settings   |
| Signal                            | #    | total voltage                  | synced with instrument database DAC settings  |
| TOF Reference                     | #    | total voltage                  | synced with instrument database DAC settings  |
| Patient Sample Sequence Time      | 15   | minutes                        | estimated time of patient sample sequence   |
| CD4 Control Sequence Time         | 18   | minutes                        | estimated time of CD4 control sequence  |
| External Control Sequence Time    | 18   | minutes                        | estimated time of external control sequence   |
| Startup Sequence Time             | 7    | minutes                        | estimated time startup sequence   |

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|  PointCare<br>Technologies Inc. | SYSTEM REQUIREMENT SPECIFICATION           | Document<br>Number:<br>SRS 005 | Rev .F |
| Effective Date:<br>8/24/2006  | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 29 of 39                  |        |

|                                      |     |   |  |
|--------------------------------------|-----|---|--|
| Clean Sequence Time                  | 10  | minutes                                   | estimated time of clean sequence   |
| Shutdown Sequence Time               | 79  | minutes                                   | estimated time of shutdown sequence  |
| Startup After Shipment Sequence Time | 82  | minutes                                   | estimated time of Startup After Shipment Sequence  |
| Shutdown For Shipment Sequence Time  | 9   | minutes                                   | estimated time of Shutdown For Shipment Sequence   |
| Enable Long Time Outs                | 0   | 0=TO based on cmd, 1=100s TO for all cmds | 0 = appropriate timeout value set for each command sent to flow cytometer. 1 = 100s timeout value set for all commands sent to flow cytometer  |
| External Control Tube Mode           | 0   | 0=75mm, 1=60mm                            | 0 = 75mm external control tube height, 1 = 60mm external control tube height   |
| Max Angle                            | 400 | bins                                      | Algorithm set up (all sample types)  |
| Extended Startup Idle Time           | 96  | Hours                                     | Time limit that instrument can be shut down before operator is forced to run an Extended Startup Cycle   |
| Do Extended Startup                  | 1   | 1 do extended startup, 0 off              | Do/do not force operator to run an Extended Startup Cycle when the instrument has been shut down for at least the "Extended Startup Idle Time" |

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 30 of 39                  |        |

## Appendix B: cluster1.ini Parameters

```
[DXBP]
ID= 1234 // last four digits of instrument serial# or 1234 if simulation
[Modes]
SampleType= 1 // 1=patient, 3=CD4CtrlNorm, 8=ExtCtrl
ReportMode= 1 // "Report Mode" service parameter
Silent= 1 // 1 = Round results w/o display, 0 = plot data w/o rounding
// ("Show Plots" service parameter)
DwellTime= 0 // Display Time 1 - 60000 seconds (If Silent = 0, then
// DwellTime = 30000
BatchPrint= 0 // "Auto Print" service parameter

[Sample]
Wbc_Offset= 0 // "WBC Offset" service parameter * 100
Wbc_Coeff= 100 // "WBC Coefficient" service parameter * 100
Lym_Offset= 0 // "LYM Offset" service parameter * 100
Lym_Coeff= 100 // "LYM Coefficient" service parameter * 100
Cd4_Offset= 0 // "CD4 Offset" service parameter * 100
Cd4_Coeff= 100 // "CD4 Coefficient" service parameter * 100
X_Center_Max= 100 // "X Center Max" service parameter
X_Center_Min= 60 // "X Center Min" service parameter
Y_Center_Max= 55 // "Y Center Max" service parameter
Y_Center_Min= 10 // "Y Center Min" service parameter
Lymph_X_Default= 70 // "Lymph X Default" service parameter
Lymph_Y_Default= 40 // "Lymph Y Default" service parameter
Default_Height= 20 // "Default Height" service parameter
DefaultWidth= 16 // "Default Width" service parameter
FSL_Thresh= 64 // "FSL Thresh" service parameter
FSH_Thresh= 64 // "FSH Thresh" service parameter
Center_Stability= 0 // "Center Stability" service parameter
Max_Events= 35000 // "Max Events" service parameter
Sample_Volume= 25 // "Sample Volume" service parameter
Sheath_Volume= 25 // "Sheath Volume" service parameter
Lyse_Volume= 700 // "Volume A" service parameter + "Volume B" service parameter
+ "Volume C" service parameter
Max_Angle= 300 // "Max Angle" service parameter

[Control]
Wbc_Offset= 0 // CD4 Control section
Wbc_Coeff= 100 // "CD4 Control WBC Offset" service parameter * 100
Lym_Offset= 0 // "CD4 Control LYM Offset" service parameter * 100
Lym_Coeff= 100 // "CD4 Control LYM Coefficient" service parameter * 100
Cd4_Offset= 0 // "CD4 Control CD4 Offset" service parameter * 100
Cd4_Coeff= 100 // "CD4 Control CD4 Coefficient" service parameter * 100
X_Center_Max= 75 // "CD4 Control X Center Max" service parameter
X_Center_Min= 45 // "CD4 Control X Center Min" service parameter
Y_Center_Max= 120 // "CD4 Control Y Center Max" service parameter
Y_Center_Min= 0 // "CD4 Control Y Center Min" service parameter
Lymph_X_Default= 70 // "CD4 Control Lymph X Default" service parameter
Lymph_Y_Default= 60 // "CD4 Control Lymph Y Default" service parameter
Default_Height= 18 // "CD4 Control Default Height" service parameter
DefaultWidth= 16 // "CD4 Control Default Width" service parameter
FSL_Thresh= 64 // "CD4 Control FSL Thresh" service parameter
FSH_Thresh= 64 // "CD4 Control FSH Thresh" service parameter
Center_Stability= 0 // "CD4 Control Center Stability" service parameter
Max_Events= 35000 // "CD4 Control Max Events" service parameter
```

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 31 of 39               |        |

```

Sample_Volume= 25          // "CD4 Control Sample Volume" service parameter
Sheath_Volume= 25          // "CD4 Control Sheath Volume" service parameter
Lyse_Volume= 700           // "Volume A" service parameter + "Volume B" service parameter
+ "Volume C" service parameter
Max_Angle= 300             // "Max Angle" service parameter

```

```

[ExternalControl]           // External Control section
Wbc_Offset= 0              // "External Control WBC Offset" service parameter * 100
Wbc_Coeff= 100              // "External Control WBC Coefficient" service parameter * 100
Lym_Offset= 0               // "External Control LYM Offset" service parameter * 100
Lym_Coeff= 100              // "External Control LYM Coefficient" service parameter * 100
Cd4_Offset= 0               // "External Control CD4 Offset" service parameter * 100
Cd4_Coeff= 100              // "External Control CD4 Coefficient" service parameter * 100
X_Center_Max= 75            // "External Control X Center Max" service parameter
X_Center_Min= 45            // "External Control X Center Min" service parameter
Y_Center_Max= 120           // "External Control Y Center Max" service parameter
Y_Center_Min= 0              // "External Control Y Center Min" service parameter
Lymph_X_Default= 70          // "External Control Lymph X Default" service parameter
Lymph_Y_Default= 60          // "External Control Lymph Y Default" service parameter
Default_Height= 18           // "External Control Default Height" service parameter
DefaultWidth= 16             // "External Control Default Width" service parameter
FSL_Thresh= 64               // "External Control FSL Thresh" service parameter
FSH_Thresh= 64               // "External Control FSH Thresh" service parameter
Center_Stability= 0           // "External Control Center Stability" service parameter
Max_Events= 35000             // "External Control Max Events" service parameter
Sample_Volume= 25             // "External Control Sample Volume" service parameter
Sheath_Volume= 25             // "External Control Sheath Volume" service parameter
Lyse_Volume= 700              // "Volume A" service parameter + "Volume B" service parameter
+ "Volume C" service parameter
Max_Angle= 300                // "Max Angle" service parameter

```

---

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 32 of 39                  |        |

## Appendix C: FCS File Keywords

| Keyword                   | Value    | Description                  |
|---------------------------|----------|------------------------------|
| IDXChannels               | 9        | number of channels           |
| PCTAppName                | AuRICA   |                              |
| PCTAppRevision            | 2.2.8    |                              |
| IDXHGBRedLightDAC         | #        | hardware setting             |
| IDXHGBRedLightADC         | #        | hardware setting             |
| IDXHGBRedDarkADC          | #        | hardware setting             |
| IDXHGBYellowLightADC      | #        | hardware setting             |
| IDXHGBYellowDarkADC       | #        | hardware setting             |
| IDXHGBGreenLightDAC       | #        | hardware setting             |
| IDXHGBGreenLightADC       | #        | hardware setting             |
| IDXHGBGreenDarkADC        | #        | hardware setting             |
| IDXHGBBlueLightDAC        | #        | hardware setting             |
| IDXHGBBlueLightADC        | #        | hardware setting             |
| IDXHGBBlueDarkADC         | #        | hardware setting             |
| IDXHGBRedADCData[0-59]    | #        | sample HGB data              |
| IDXHGBYellowADCData[0-59] | #        | sample HGB data              |
| IDXHGBGreenADCData[0-59]  | #        | sample HGB data              |
| IDXHGBBlueADCData[0-59]   | #        | sample HGB data              |
| IDXCounter[001-071]       | #        | event count for each FIFO    |
| IDXTimer[001-071]         | #        | FIFO time for each FIFO      |
| IDXEventCount             | #        | summation of counts per FIFO |
| IDXChannel1               | FSL Peak | channel name                 |
| IDXChannel2               | FSH Peak | channel name                 |
| IDXChannel3               | EXT Peak | channel name                 |
| IDXChannel4               | EXT Int  | channel name                 |
| IDXChannel5               | RAS Peak | channel name                 |
| IDXChannel6               | RAS Int  | channel name                 |
| IDXChannel7               | TOF      | channel name                 |

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 33 of 39                  |        |

|                           |            |   |
|---------------------------|------------|---|
| IDXChannel8               | REF        | channel name  |
| IDXChannel9               | EventTime  | channel name  |
| PCTInstrumentSerialNumber | DXBP00XXXX |   |
| PCTPatientId              | xyz        | ID of current patient or lot number of current control material   |
| PCTClinic                 | xyz        | Clinic name   |
|                           | #          |   |
| PCTPatientMode            |            | PatientSample=0, WBCI=1, WBCII=2, WBCIII=3, CD4CtrL=4, CD4CtrL=5, ExtCtrl=6                               |
| PCTSampRate               | 0.76       | "WBCSampleRate" from Instrument DB  |
| PCTAnalyzedSampleVolume   | #          | PCTSampRate * summation of FIFO times   |
| IDXCellTypeAnalyzed       | White      |   |
| PCTReadTime               | 35         | Theoretical analysis time in seconds  |
| PCTFIFOTime               | 0.3        | "Fifo Time" service parameter / 1000  |
| PCTDuration               | #          | summation of FIFO times (actual analysis time) in seconds   |
| PCTAirGapBlood            | 15         | "AirGapWholeSample" from Instrument DB  |
| PCTAirGapLyse1            | 75         | "Air 1 Volume" service parameter  |
| PCTAirGapLyse2            | 75         | "Air 2 Volume" service parameter  |
| PCTAirGapDilutedSample    | 60         | "AirGapDilutedSample" parameter from Instrument DB  |
| PCTSampType               | #          | patient=1, CD4CtrlNorm=3, ExtCtrl=8   |
| PCTReportMode             | 1          | "Report Mode" service parameter   |
| PCTWBCOffset              | #          | "WBC Offset", "CD4 Control WBC Offset", or "External Control WBC Offset" service parameter                |
| PCTWBCCoeff               | #          | "WBC Coefficient", "CD4 Control WBC Coefficient", or "External Control WBC Coefficient" service parameter |
| PCTLYMOFFSET              | #          | "LYM Offset", "CD4 Control LYM Offset", or "External Control LYM Offset" service parameter                |
| PCTLYMCoeff               | #          | "LYM Coefficient", "CD4 Control LYM Coefficient", or "External Control LYM Coefficient" service parameter |
| PCTCD4Offset              | #          | "CD4 Offset", "CD4 Control CD4 Offset", or "External Control CD4 Offset" service parameter                |
| PCTCD4Coeff               | #          | "CD4 Coefficient", "CD4 Control CD4 Coefficient", or "External Control CD4 Coefficient" service parameter |

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 34 of 39               |        |

|                    |       |  |
|--------------------|-------|--|
| PCTXCenterMax      | #     | "X Center Max", "CD4 Control X Center Max", or "External Control X Center Max" service parameter             |
| PCTXCenterMin      | #     | "X Center Min", "CD4 Control X Center Min", or "External Control X Center Min" service parameter             |
| PCTYCenterMax      | #     | "Y Center Max", "CD4 Control Y Center Max", or "External Control Y Center Max" service parameter             |
| PCTYCenterMin      | #     | "Y Center Min", "CD4 Control Y Center Min", or "External Control Y Center Min" service parameter             |
| PCTLymphXDefault   | #     | "Lymph X Default", "CD4 Control Lymph X Default", or "External Control Lymph X Default" service parameter    |
| PCTLymphYDefault   | #     | "Lymph Y Default", "CD4 Control Lymph Y Default", or "External Control Lymph Y Default"                      |
| PCTDefaultHeight   | #     | "Default Height", "CD4 Control Default Height", or "External Control Default Height" service parameter       |
| PCTDefaultWidth    | #     | "Default Width", "CD4 Control Default Width", or "External Control Default Width" service parameter          |
| PCTFSLThresh       | #     | "FSL Thresh", "CD4 Control FSL Thresh", or "External Control FSL Thresh" service parameter                   |
| PCTFSHThresh       | #     | "FSH Thresh", "CD4 Control FSH Thresh", or "External Control FSH Thresh" service parameter                   |
| PCTCenterStability | #     | "Center Stability", "CD4 Control Center Stability", or "External Control Center Stability" service parameter |
| PCTMaxEvents       | 35000 | "Max Events", "CD4 Control Max Events", or "External Control Max Events" service parameter                   |
| PCTSsampleVolume   | #     | "Sample Volume", "CD4 Control Sample Volume", or "External Control Sample Volume" service parameter          |
| PCTSsheathVolume   | #     | "Sheath Volume", "CD4 Control Sheath Volume", or "External Control Sheath Volume" service parameter          |
| PCTLyseVolume      | #     | "Volume A" service parameter + "Volume B" service parameter + "Volume C" service parameter                   |
| PCTMaxAngle        | 300   | "Max Angle" service parameter  |
| PCTBarcodeLyse     | #     | barcode string read from lyse tube   |

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 35 of 39                  |        |

|                   |           |   |
|-------------------|-----------|---|
| PCTBarcodeQuench  | #         | barcode string read from quench tube  |
| PCTBarcodeReagent | #         | barcode string read from gold reagent tube  |
| PCTBarcodeSample  | #         | barcode string read from patient sample or control tube   |
| \$PAR             | 9         | total number of parameters (channels)   |
| \$TOT             | #         | total number of objects for which data are stored   |
| \$NEXTDATA        | 0         | byte offset of additional data set within file, 0=none  |
| \$BYTEORD         | 1,2       | order in which data bytes are written   |
| \$MODE            | L         | U=uncorrelated single-parameter histograms, C=one correlated multiparameter histogram,<br>L=list mode             |
| \$DATATYPE        | I         | I=unsigned, binary integers, F=32-bit floating point numbers, D=64-bit floating point numbers,<br>A=ASCII encoded |
| \$PnB             | 16        | number of bits for each data point for parameter n (0-9)  |
| \$PnR             | 16384     | parameter n (0-9) range   |
| \$PnE             | 0,0       | parameter n (0-9) method of amplification   |
| \$P1N             | FSL Peak  | parameter 1 name  |
| \$P2N             | FSH Peak  | parameter 2 name  |
| \$P3N             | EXT Peak  | parameter 3 name  |
| \$P4N             | EXT Int   | parameter 4 name  |
| \$P5N             | RAS Peak  | parameter 5 name  |
| \$P6N             | RAS Int   | parameter 6 name  |
| \$P7N             | TOF       | parameter 7 name  |
| \$P8N             | REF       | parameter 8 name  |
| \$P9N             | EventTime | parameter 9 name  |

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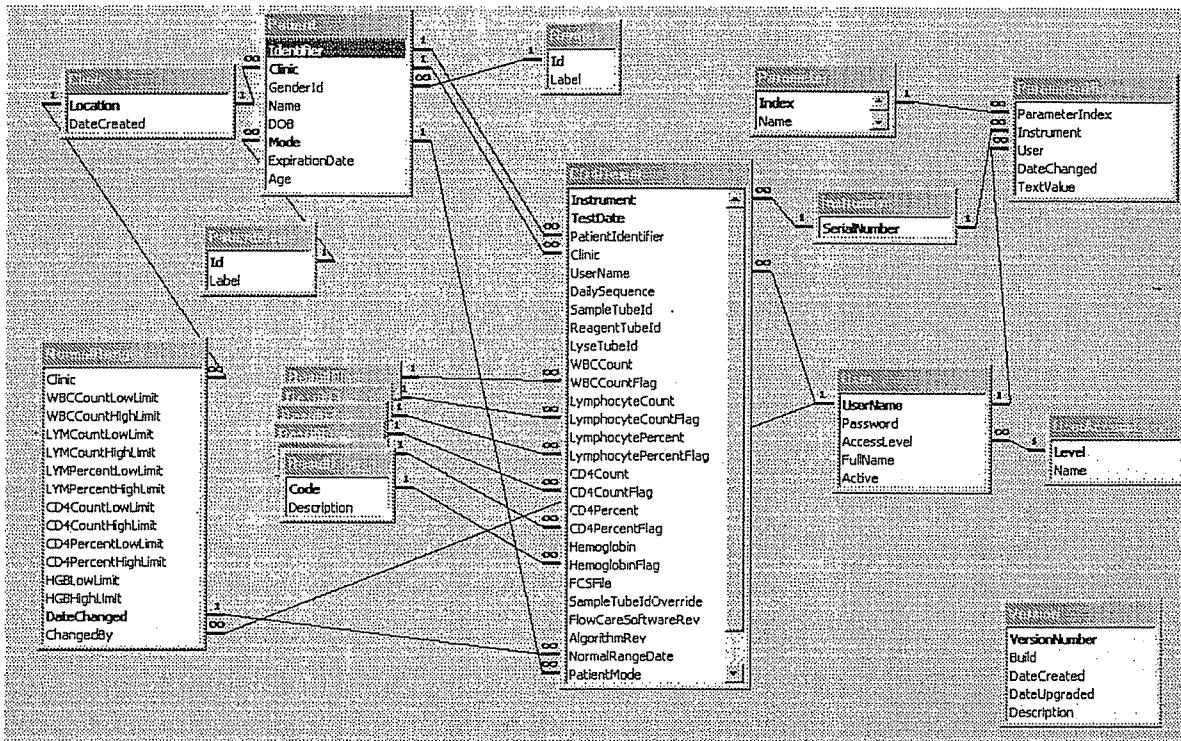
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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 36 of 39                  |        |

## Appendix D: AuRICA.mdb Relationship Diagram

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 38 of 39               |        |

## Appendix E: Barcode Label Formats

### Barcode Format For Large Tubes

Example: 46119001

| 4<br>Id     | 6<br>Exp. Yr. | 119<br>Exp. Day/Mfg. Month | 001<br>Seq. #     |
|-------------|---------------|----------------------------|-------------------|
| before 2015 | 5=2005/2015   | tubes that expire:         | 0-999 (repeating) |
| 1=lyse      | 6=2006/2016   | 1-366                      |                   |
| 2=waste     | 7=2007/2017   |                            |                   |
| 3=quench    | 8=2008/2018   | waste tube                 |                   |
| 4=clean     | 9=2009/2019   | (does not expire):         |                   |
|             | 0=2010/2020   | 901=jan                    |                   |
| 2015+       | 1=2011/2021   | 902=feb                    |                   |
| 5=lyse      | 2=2012/2022   | 903=mar                    |                   |
| 6=waste     | 3=2013/2023   | 904=apr                    |                   |
| 7=quench    | 4=2014/2024   | 905=may                    |                   |
| 8=clean     |               | 906=jun                    |                   |
|             |               | 907=jul                    |                   |
|             |               | 908=aug                    |                   |
|             |               | 909=sep                    |                   |
|             |               | 910=oct                    |                   |
|             |               | 911=nov                    |                   |
|             |               | 912=dec                    |                   |

### Barcode Format For Gold Tubes

Example: G6119001

| G<br>Id | 6<br>Exp. Yr. | 119<br>Exp. Day | 001<br>Seq. #     |
|---------|---------------|-----------------|-------------------|
| G=gold  | 5=2005        | 1-366           | 0-999 (repeating) |
|         | 6=2006        |                 |                   |
|         | 7=2007        |                 |                   |
|         | 8=2008        |                 |                   |
|         | 9=2009        |                 |                   |
|         | 0=2010        |                 |                   |
|         | 1=2011        |                 |                   |
|         | 2=2012        |                 |                   |
|         | 3=2013        |                 |                   |
|         | 4=2014        |                 |                   |

### Barcode Format For Patient Sample Tubes

Example: P1234567

|         |                   |
|---------|-------------------|
| P<br>Id | 1234567<br>Seq. # |
|---------|-------------------|

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| Effective Date:<br>8/24/2006   | TITLE: SEQUENCE REQUIREMENTS SPECIFICATION | Page 39 of 39                  |        |

P=patient 0-9999999

Barcode Format For CD4 Control Tubes  
 Example: 712345001

|                         |        |
|-------------------------|--------|
| 712345                  | 001    |
| Lot#                    | Seq. # |
| 6 digit Immunotrol Lot# | 0-999  |

END OF DOCUMENT

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**EXHIBIT 4**

**From:** Karl Gu  
**Sent:** 12/13/2006 11:36:55 PM  
**To:** Andrea Desrosiers  
**CC:** jwerner@capsher.com; jwaite@pointcaretechnologies.com; debarry@pointcare.net; Andrew Kenney; Gary Young  
**Subject:** RE: back in Boston

Hi Andrea,

Attached is the meeting minutes. If you see anything missing, please let me know and we can add to the doc.

Regards,  
Karl

---

From: Andrea Desrosiers [mailto:[adesrosiers@pointcare.net](mailto:adesrosiers@pointcare.net)]  
Sent: Wednesday, December 13, 2006 3:22 PM  
To: Karl Gu  
Subject: back in Boston

Hello Karl,

Thank you very much for sending Jen the Validation Plan. It will save us a great deal of typing as we create our own test procedure.

Amy had said something to Don about requesting a user interface document. Do you know what she is talking about? Please drop me an email if you need anything from us. I am currently working on our trip report, but I won't be able to complete it until Jen returns on Monday. Do you know when Jason might have the meeting minutes summarized?

Sincerely,  
Andrea Desrosiers

Attachment: CD4 Software Project Status Meeting2.doc

Drew Scientific Inc.

Document Title: CD4 Customer Software Project Status Meeting

Author: Jason Werner, Karl Gu

Date: December 13, 2006

**Summary:**

This document describes the points discussed during the meeting between Drew Scientific and PointCare, along with the action points for each person attending.

**Attendees:**

| Name              | Initial | Title              | Company            |
|-------------------|---------|--------------------|--------------------|
| Karl Gu           | KG      | Software Engineer  | Drew Scientific    |
| Andrea Desrosiers | AD      | Software Manager   | PointCare          |
| Jennifer Waite    | JW      | Software Engineer  | PointCare          |
| William Ross      | WR      | Validation Manager | Drew Scientific    |
| Jason R Werner    | JRW     | Software Developer | Capsher Technology |

**Status of User Interface Software:**

The user interface software is close to 50% done and PointCare team estimate to finish all required changes by end of January 2007. KG suggests PointCare considering use external resources as needed to speed the process and meet deadline.

**Meeting Topics:**

**1. Validation**

**Points Discussed:**

- It was decided that both PointCare and Drew Scientific would be responsible for writing their own validation procedures.

**Action Items:**

- WR is responsible for the validation document for Drew Scientific.
- AD is responsible for ensuring that the validation document is written for PointCare.
- Drew Scientific will provide PointCare with the current validation document for the EXCELL 2280 analyzer.

**2. Integration**

Drew Scientific Inc.

---

Points Discussed:

- JRW and KG will lead the integration user interface part of the software project. This currently consists of helping with integration issues related to the User Interface, CD4 dll, ActiveX controls, calculation utilities, and autosampler logic.

Action Items:

- JRW/KG will assist Jennifer Waite with Autosampler logic questions and ensure that the code logic is correct.
- JRW will complete and send ActiveX controls to PointCare and assist with integration of each control.

### 3. PointCare Issues

Points Discussed:

- Screen resolution of 800X600 looks bad on current touch screens and no solution found yet.
- PointCare needs to determine barcode format for CBC/CD4 controls and samples.
- Need to determine when the computer is operating off of UPS.

### 4. UI Tasks Remaining

Points Discussed:

- Major tasks written in the Aurica HT User Interface Tasks document were reviewed by AD, KG, JRW, and Jennifer Waite.
- Each task written in the Aurica HT User Interface Tasks document was later reviewed again by JRW and Jennifer Waite to estimate development time.
- Screen layout will be changed on major screens by writing layout function.
- Unused control buttons will be hidden on menu.

Action Items:

- JW will make a check list for each item remaining so that it can be checked off as it is completed.
- JW is working on having the UI tasks completed by the end of January.
- JW is responsible for modifying all screens to use the new graphics.
- JW will implement hiding of unused buttons.

### 5. Image Buttons

Points Discussed:

- Image buttons will contain both an image and text. The text will be on the lower portion of the button.

Drew Scientific Inc.

- Image display will be configurable so that it can be enabled and disabled to meet both PointCare and Drew Scientifics needs.
- All buttons on main screen will contain images.

Action Items:

- JW will work with Dennis Chappell to design new image buttons that are square instead of round. Only make changes for a couple of screens first and proceed after input from marketing.
- JW will integrate the new buttons into the software and make the image display configurable. This includes all normal user accessible screens.

**6. Results screens**

Points discussed:

- The software was modified to use only *one* results screen, but it was decided to use *two* results screens to remove any confusion in the logic behind the scenes.

Action Items:

- JW will reverse the software back to use two results screens instead of one to remove any confusion.

**7. Calibration Samples**

Points discussed:

- Calibration samples will be run separate from other samples.
- Calibration tube will be placed in position 1 of the carousel.
- The logic for running the calibration samples will be similar to the batch processing.

Action Items:

- JW will modify the software handle configuration a calibration sample. The user will be able to define the number of times a calibration sample is processed as specified in the original user interface change document.

**8. Autosampler Logic**

Points discussed:

- The autosampler logic was discussed and detailed by KG, JW, and JRW.
- Three different logical procedures were discussed: Preparing Work Queue, Running a Batch, and Running a Stat.

Action Items:

Drew Scientific Inc.

---

- JRW will create flow charts detailing the logical procedures followed for each scenario.
- KG will verify flow charts.
- Basic logic is in place and JW will implement the remaining change in software.

**9. Installation**

Points discussed:

- The installation procedure will need to be modified for the Aurica software. There were questions related to how this can be modified.
- The software will need to be installed from a USB removable drive.

Action Items:

- AD? will be looking into how this is currently being done and figure out how this should be modified.

**10. CD4 Algorithm**

Points discussed:

- The API for the CD4 dll was discussed, which consisted of three basic functions as outlined by KG: *LoadCD4Param*, *CalculateCD4*, and *ReadCD4*.
- Also discussed was the integration of the dll into the existing architecture. The CD4 dll will be available to both the CBC dll and the VB app.
- The computation time is too long. User interface may be frozen for over 20 seconds and user input could be lost.

Action Items:

- AD will be working with another person from PointCare on implementing the discussed interface for the CD4 algorithm dll. CD4 configuration parameters need to be provided to implement the dialogue screen in service software.
- AD will make the CD4 dll run faster and not freeze the user interface.
- JRW/KG will be assist with questions related to integration of the dll into the software.

**EXHIBIT 5**

Following email is in regards to the phone conversation we had earlier today. As discussed Andrew and I will be available for a conference call re:software first of next week when Peter is available.

Doug,

-----Original Message-----

From: Andrew Kenney [mailto:[andrewk@drew-scientific.com](mailto:andrewk@drew-scientific.com)]  
Sent: Wednesday, December 13, 2006 10:58 AM  
To: Doug Nickols; Frank Matuszak  
Subject: PointCare & software effort

We are running into a problem with the work PC is doing on the software.

It was due in September, then Thanksgiving, now January. This is looking like the critical path right now Karl thinks they are spending more time in France than on our work and that they have been told to give C2 priority. They are expecting a June launch apparently!

I have asked Gary to complain to Don that this work is slipping badly.

You might want to complain higher up - or I will if you want.

Andrew

## **EXHIBIT 6**

**From:** Jennifer Waite  
**Sent:** 1/9/2007 10:17:23 PM  
**To:** Karl Gu  
**CC:** jwerner@capsher.com; Andrea Desrosiers  
**Subject:** RE: ActiveX control

Hi Karl,

Here's my updated list. I know it looks like there's a lot left to do... but I'm pretty confident I'll have all of the coding done by the end of the month. It might not necessarily work perfectly on the instrument right away... I will need to spend time with the prototype early Feb to troubleshoot and verify the code.

-Jen

Jennifer Waite

Software Engineer  
PointCare Technologies, Inc.  
tel: (508) 281-6926 x15  
fax: (508) 281-6930  
jwaite@pointcare.net

-----Original Message-----

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]  
Sent: Tuesday, January 09, 2007 5:07 PM  
To: Jennifer Waite  
Subject: RE: ActiveX control

Hi Jen,

Thanks for the updated doc.

How's the UI developement? Are we confident to finish all outstanding items this month?

Regards,  
Karl

-----Original Message-----

From: Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
Sent: Tue 1/9/2007 4:57 PM  
To: Karl Gu  
Cc: [jwerner@capsher.com](mailto:jwerner@capsher.com)  
Subject: RE: ActiveX control

Karl,

Here is an updated barcode doc. We added another ID character for the patient and control tubes. CD4 patient sample barcodes will start with "PT" instead of just "P" and CD4 control barcodes will start with a "CT" instead of just "C".

-jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

tel: (508) 281-6926 x15

fax: (508) 281-6930

[jwaite@pointcare.net](mailto:jwaite@pointcare.net)

-----Original Message-----

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]  
Sent: Monday, January 08, 2007 12:02 PM  
To: Jennifer Waite  
Cc: [jwerner@capsher.com](mailto:jwerner@capsher.com); Andrea Desrosiers  
Subject: RE: ActiveX control

Hi Jen,

I have a problem with the proposed barcode format for patient and control. The format is too generic and there are only one letter P or C

plus some digits. We could easily have a patient barcode starting from a letter D with some digits. This could be a problem to treat the tube as control instead of patient. At minimum, we need to have two letters. However, if Pointcare do want the format with no change, we can implement it.

Regards,

Karl

---

From: Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
Sent: Friday, January 05, 2007 2:18 PM  
To: Karl Gu  
Cc: [jwerner@capsher.com](mailto:jwerner@capsher.com); Andrea Desrosiers  
Subject: RE: ActiveX control

Hi Karl,

Thanks for sending the ActiveX Controls! I hope to be able to test them out next week! Attached is a document answering your questions about barcodes and reagent colors. Andrea will be sending you the CD4 configuration parameters.

I will also be sending you my updated To Do list on Monday.

-Jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

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[jwaite@pointcare.net](mailto:jwaite@pointcare.net)

-----Original Message-----

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]  
Sent: Wednesday, January 03, 2007 2:41 PM  
To: Jennifer Waite

Cc: jwerner@capsher.com; Andrea Desrosiers  
Subject: ActiveX control

Hi Jen,

Jason finished the ActiveX controls along with documents. Please try the ActiveX control.

We are close to finish the Service software and Jason will soon finish all his assignment related with this project. If you or Andrea could give us the CD4 configuration parameters, Jason can put it in service software. Also we need to have the CD4 patient, CD4 control barcode formats, and CD4 control cap color, CD4 Reagent color. Please put this in a simple document.

Regards,

Karl

Attachment: AuRICA HT UI TODO.xls

**EXHIBIT 7**

**From:** Karl Gu  
**Sent:** 2/7/2007 1:56:27 AM  
**To:** Don Barry  
**CC:**  
**Subject:** RE: UI CD4

Hi Don,

This all depends on the CD4 dll (Andrea), UI (Jen), and decks (George). When these are finished, I can deliver a working service software with all the other required firmware in one week. After that, there are more work to do, depending the quality of the code delivered.

If I cannot get the UI and CD4 dll, it is impossible to do any further integration.

Regards,

-----Original Message-----

From: Don Barry [mailto:[debarry@pointcare.net](mailto:debarry@pointcare.net)]  
Sent: Tue 2/6/2007 8:35 PM  
To: Karl Gu  
Subject: RE: UI CD4

Hi Karl,

Assuming that the software will be finished by Friday, will there be any subsequent delays from your end with regards to software integration? I realize that the delivery of the software is already a week late from the last scheduled date. Please let me know if there have been any changes.

thanks,  
Don

-----Original Message-----

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]  
Sent: Tue 2/6/2007 6:57 PM  
To: Jennifer Waite  
Cc: Andrea Desrosiers; Don Barry; Dorothy Branco  
Subject: RE: UI CD4

Hi Jen,

I really do not want to see any key code being commented out in VB at this stage. If the CD4 dll is not ready by this Friday, please hardcode the cut algorithm but keep the API accessible from the UI. We need the CD4 dll to proceed the integration work - VB, Hematology dll, and Service software.

For the screen, I will pick the blue one.

Thank you for the update.

Regards,  
Karl

-----Original Message-----

From: Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
Sent: Tue 2/6/2007 6:10 PM  
To: Karl Gu  
Cc: Andrea Desrosiers; Don Barry; Dorothy Branco  
Subject: RE: UI CD4

Hi Karl,

Attached is my updated to-do list. I'm planning on having all high priority tasks completed by Friday. Our CD4.dll might not be quite ready for action by then... if that is the case I will send you the UI code with those function calls commented out.

I've also attached a couple of screen shots... Which button background color do you think looks the best? Don, Andrea, & Dorothy... please let me know what you think about that as well.

Best Regards,

Jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

tel: (508) 281-6926 x15

fax: (508) 281-6930

[jwaite@pointcare.net](mailto:jwaite@pointcare.net)

-----Original Message-----

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]  
Sent: Tuesday, February 06, 2007 10:34 AM

To: Jennifer Waite  
Subject: UI CD4

Hi Jen,

Could you give a update about the UI? When do you think that UI will be finished?

Regards,  
Karl

|      | A   | B        | C        | D  | E      | F             |
|------|---|----------|----------|--|--------|---------------|
| 1    | AURICQA HT User Interface To-Do List - Release 1  |          |          |  |        |               |
| 2    | Maintained By: Jennifer Waite   |          |          |  |        |               |
| 3    | Status Codes: <u>Open</u> , <u>Coded</u> , <u>Verified</u> , <u>On Hold</u>                           |          |          |  |        |               |
| 4    | Priority Codes: <u>1</u> : High, <u>2</u> : Medium, <u>3</u> : Low                                    |          |          |  |        |               |
| Item | Description   | Priority | Priority | Description  | Status | Date Verified |
| 10   |   |          |          |  |        |               |
| 11   | <b>GENERAL</b><br>The screen resolution for the user interface will be kept at 800x600 for Release 1. | 1        | 1        | The screen resolution for the user interface will be kept at 800x600 for Release 1.  | V      | 30-Sep        |
| 12   |   | 2        | 1        | There will be a single executable for the PointCare and Drew User Interface for Release 1.   | V      | 30-Sep        |
| 13   |   | 3        | 1        | For CD4 reporting, there will be 2 FCS files created: one for the 1st pass with no gold, one for the 2nd pass with gold.   | C      | 30-Sep        |
| 14   |   | 4        | 1        | Remove option for user to run sample in "Direct Mode" (open tube).   | V      | 30-Sep        |
| 15   |   | 5        | 1        | Make all buttons larger for touch screen use.  | V      | 30-Sep        |
| 16   |   | 6        | 1        | Use "Back" or up arrow icon instead of "Exit" on all F9 buttons except on Main Menu.   | V      | 30-Sep        |
| 17   |   | 7        | 3        | Change all date entry text boxes to drop down menus for localization.  | O      |               |
| 18   |   | 8        | 1        | Remove Worklist and Mode fields from all screens as these are related with Direct Mode sampling.   | V      | 30-Sep        |
| 19   |   | 9        | 1        | Remove Type fields from all screens except the Auto Sampler screen.  | V      | 30-Sep        |
| 20   |   | 10       | 1        | Change screen layout on non-service screens to use new graphics scheme<br>Image buttons will contain both an image and text. The text will be on the lower portion of the button. Only high level and common buttons will have images. | V      | 7-Jan         |
| 21   |   | 11       | 1        | Make button image display configurable   | C      |               |
| 22   |   | 12       | 1        | Unused buttons will be hidden  | V      | 7-Jan         |
| 23   |   | 13       | 1        | Function keys for buttons will not be supported anymore.   | V      | 7-Jan         |
| 24   |   | 14       | 1        | Tab key should jump through all buttons on screen  | V      | 7-Jan         |
| 25   |   | 15       | 2        | Need to determine when computer is operating off of UPS  | H      |               |
| 26   |   | 16       | 2        | Link in new CD4.dll library to call LoadCD4Parameters() and ReadCD4Results() functions.  | O      |               |
| 27   |   | 17       | 1        | Need custom pop-up message box that have larger Yes/No/Ok/Cancel buttons for use with touch screen   | O      |               |
| 28   |   | 18       | 2        |  |        |               |
| 29   |   |          |          |  |        |               |
| 30   |   |          |          |  |        |               |
| 31   | <b>LOGIN SCREEN</b>   |          |          |  |        |               |
| 32   |   | 19       | 1        | Create 3 user levels: Service, Administrator, Technician   | V      | 30-Oct        |
| 33   |   | 20       | 1        | Login Screen will have drop down menu for choosing a user name   | V      | 30-Oct        |
| 34   |   | 21       | 1        | Initial login after install will contain only one user   | H      |               |
| 35   |   | 22       | 1        | "Service" user will have an unchangeable username and password   | V      | 6-Feb         |
|      |   | 23       | 1        | "Service" user can create multiple Technician and Administrator users and change their passwords.  | V      | 6-Feb         |

|    | G   |
|----|---|
| 1  | % of Total  |
| 2  | 14%   |
| 3  | 10%   |
| 4  | 73%   |
| 5  | 3%  |
| 6  |   |
| 7  |   |
| 8  | Notes   |
| 9  |   |
| 10 |   |
| 11 |   |
| 12 |   |
| 13 |   |
| 14 |   |
| 15 |   |
| 16 |   |
| 17 |   |
| 18 |   |
| 19 |   |
| 20 |   |
| 21 | Dennis delivered first set of images on 1/17/07, 2nd set on 2/5/07                            |
| 22 | need to propagate code to all forms containing button images                                  |
| 23 |   |
| 24 |   |
| 25 |   |
| 26 | Need UPS<br>Calls to ReadCD4Results() have been commented out until<br>CD4.dll file is ready. |
| 27 |   |
| 28 | this applies to all forms with small buttons  |
| 29 |   |
| 30 |   |
| 31 |   |
| 32 |   |
| 33 | Final Excel24.mdb will have only "Service" user in database when<br>installed.                |
| 34 | need Encryption utility to encrypt/decrypt passwords  |
| 35 |   |

| A  | B | C  | D   | E | F      |
|----|---|----|---|---|--------|
| 35 |   | 24 | "Administrator" user can create multiple Technician users and change their<br>1<br>passwords.   | V | 5-Feb  |
| 37 |   | 25 | All prompts for operator initials need to be removed because operator<br>1<br>username will be used.  | V | 30-Oct |
| 38 |   | 26 | Replace reagent consumption progress bars with new ActiveX control  | V |        |
| 39 |   |    | <b>MAIN MENU</b>  |   |        |
| 40 |   |    |   |   |        |
| 41 |   | 27 | 1 Add 2 progress bars for monitoring Gold and CD4 Reagent fluid levels.   | V | 30-Sep |
| 42 |   | 28 | 1 Run button brings up Auto Sampler Screen instead of Run Menu Screen.  | V | 30-Oct |
| 43 |   | 29 | Autosampler status must be queried before the Autosampler Run Screen is<br>1<br>showed.   | C |        |
| 44 |   | 30 | 1 Calibration button grayed if user is Technician   | V | 30-Oct |
| 45 |   |    | <b>STARTUP AND SHUTDOWN MENU</b>  |   |        |
| 46 |   |    |   |   |        |
| 47 |   | 31 | 1 Add 2 progress bars for monitoring Gold and CD4 Reagent fluid levels.   | V | 30-Sep |
| 48 |   | 32 | 1 Add "Logout" button which will bring up the login screen.   | V | 30-Oct |
| 49 |   | 33 | 1 After shutdown sequence is completed, bring up the login screen.<br>"Wake Up" function runs Startup behind the scenes to put instrument in<br>Ready state. Once user logs back in, the instrument is ready to perform a<br>1<br>test. | V | 30-Oct |
| 50 |   | 34 | 1 User can log out without running a shutdown. The auto shutdown will start at<br>1<br>scheduled time.  | C |        |
| 51 |   | 35 |   |   |        |
| 52 |   |    |   |   |        |
| 53 |   |    | <b>WORKLIST MENU</b>  |   |        |
| 54 |   |    |   |   |        |
| 55 |   | 36 | <b>A. Edit Worklist</b>   |   |        |
| 56 |   |    | 1 Remove "Add Sample" Button  | V | 30-Nov |
| 57 |   |    | Reorder remaining buttons: Add Sample Carousel 1, Add Sample Carousel 2,  |   |        |
| 58 |   | 37 | 1 Add Sample Carousel 3, Revise Selection, Delete Selection   | V | 30-Nov |
| 59 |   | 38 | 1 Add column for "Collection Time" in Worklist table.   | V | 30-Nov |
| 60 |   | 39 | 1 Change Print function to account for new fields in Worklist table.  | V | 9-Jan  |
| 61 |   |    | B. Add Carousel 1/2/3 Menu  |   |        |
| 62 |   | 40 | 1 Add "Sample Collection Time" field  | V | 30-Nov |
| 63 |   |    | Add radio buttons for "CBC only" and "CBC with CD4", default = "CBC with<br>1<br>CD4".  | V | 30-Nov |
| 64 |   | 41 | Remove Male/Female buttons and add Gender drop down list with values:<br>1<br>Male, Female, Unspecified   | V | 30-Nov |
| 65 |   | 42 | 1 Male, Female, Unspecified   | V | 30-Nov |
| 66 |   | 43 | 1 Add buttons for CD4 Low Control and CD4 Normal Control  | V | 30-Nov |
| 67 |   | 44 | Reorder buttons: Find Match by Patient ID, Find Match by Name, Low<br>Control, Normal Control, High Control, CD4 Low Control, CD4 Normal<br>Control, Save, Exit.  | V | 30-Nov |
| 68 |   | 45 | <b>C. Revise Selection Menu</b>   |   |        |
|    |   | 46 | 1 Add "Sample Collection Time" field  | V | 30-Nov |
|    |   | 47 | Add radio buttons for "CBC only" and "CBC with CD4", default = "CBC with<br>1<br>CD4".  | V | 30-Nov |
|    |   |    | Remove Male/Female buttons and add Gender drop down list with values:<br>1<br>Male, Female, Unspecified   | V | 30-Nov |

|    |   |
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|    | G   |
| 36 |   |
| 37 |   |
| 38 |   |
| 39 |   |
| 40 |   |
| 41 |   |
| 42 |   |
| 43 | code present in frmMainMenu...needs to be uncommented |
| 44 |   |
| 45 |   |
| 46 |   |
| 47 |   |
| 48 |   |
| 49 |   |
| 50 | Needs to be verified on hardware                      |
| 51 | Needs to be verified on hardware                      |
| 52 |   |
| 53 |   |
| 54 |   |
| 55 |   |
| 56 |   |
| 57 |   |
| 58 |   |
| 59 |   |
| 60 |   |
| 61 |   |
| 62 | Using blank instead of "Unspecified"                  |
| 63 | Using blank instead of "Unspecified"                  |
| 64 |   |
| 65 |   |
| 66 |   |
| 67 |   |
| 68 | Using blank instead of "Unspecified"                  |

| A   | B | C  | D  | E | F      |
|-----|---|----|--|---|--------|
| 69  |   | 48 | 1 Add buttons for CD4 Low Control and CD4 Normal Control<br>Reorder buttons: Find Match by Patient ID, Find Match by Name, Low Control, Normal Control, High Control, CD4 Low Control, CD4 Normal Control, Save, Exit. | V | 30-Nov |
| 70  |   | 49 |  | V | 30-Nov |
| 71  |   |    |  |   |        |
| 72  |   |    |  |   |        |
| 73  |   |    |  |   |        |
| 74  |   |    |  |   |        |
| 75  |   | 50 | 1 Apply new screen layout with button images designed by Dennis  | V | 30-Oct |
| 76  |   | 51 | 1 Add progress bars for monitoring all reagent fluid levels  | V | 30-Oct |
| 77  |   | 52 | 1 Keep "Type" field to differentiate between Patient and Control samples.  | V | 30-Oct |
| 78  |   | 53 | 1 Add "Run Background" button<br>Define and support reading new barcode formats for CD4 Controls and CD4 Patient Samples   | C | 30-Oct |
| 79  |   | 54 |  | O |        |
| 80  |   | 55 | 1 Remove "Stat Direct" and "Stat Saver" buttons.   | O |        |
| 81  |   | 56 | 1 By default, run is CD4   | V | 30-Oct |
| 82  |   | 57 | 3 If LIS is use, query LIS for the sample type (CD4 or CBC only).<br>Incorporate new Carousel ActiveX control in screen and function calls into  | O |        |
| 83  |   | 58 | 1 Auto Sampler logic   | O |        |
| 84  |   | 59 | 1 Group date, instrument, S/N into one green box   | V | 3-Jan  |
| 85  |   | 60 | 1 Group wake up status and XB status into one green box  | V | 3-Jan  |
| 86  |   | 61 | 1 Change Analyzer Status back to text box, not light images  | V | 3-Jan  |
| 87  |   |    |  |   |        |
| 88  |   | 62 | 1 Add CD4# and CD4% parameters to Datalog Table (Insert after Bas param)   | V | 30-Sep |
| 89  |   | 63 | 1 Move Bas after Eos and Bas% after Eos% in Datalog Table<br>Unsupported params will show up as blank in the Datalog Table and will be   | V | 30-Sep |
| 90  |   | 64 | 1 blank in the database  | V | 9-Jan  |
| 91  |   | 65 | 1 Add CD4# and CD4% parameters to data stream for Transfer function  | O |        |
| 92  |   | 66 | 1 Add CD4# and CD4% to all printouts   | V | 15-Jan |
| 93  |   | 67 | 1 Add CD4# and CD4% to statistic calculations  | V | 12-Jan |
| 94  |   | 68 | 1 Add "Find Date" button to allow user to search by a date   | V | 12-Jan |
| 95  |   | 69 | 1 Do not change Datalog table cell heights if user clicks "Change" button  | V | 9-Jan  |
| 96  |   |    |  |   |        |
| 97  |   | 70 | 1 Apply new screen layout with button images designed by Dennis  | V |        |
| 98  |   | 71 | 1 Keep Datalog Results display and Auto Sampler Results display in separate VB forms   | V |        |
| 99  |   | 72 | 1 Add "Previous" and "Next" buttons to Auto Sampler Results screen to scroll through results for current batch.  | C |        |
| 100 |   | 73 | 1 Add CD4# and CD4% result fields..keep blank for CBC only<br>Add radio buttons or drop down menu to switch 3-D plot between CBC and CD4 plot.   | C |        |
| 101 |   | 74 | 1 Add CD4 results to printout  | C |        |
| 102 |   | 75 | 1 If CD4 run, show 2-D CD4 plot instead of 2-D Eos plot in printout  | V |        |
| 103 |   | 76 | 1 Add "Edit Comments" button to AutoSampler result form  | C |        |
| 104 |   | 77 | 1 Create 2D CD4 plot   | C |        |
| 105 |   | 78 | 1 Remove animation   | C |        |
| 106 |   | 79 | 1  | V |        |

|     |   |
|-----|---|
| 69  | G   |
| 70  |   |
| 71  |   |
| 72  |   |
| 73  |   |
| 74  |   |
| 75  |   |
| 76  | Needs to be run on hardware   |
| 77  | barcode formats defined...need to put in code   |
| 78  |   |
| 79  | Works graphically, but needs testing with Auto Sampler<br>If LIS bidirectional enabled, sample type decided from LIS query, if no |
| 80  | sample type returned, use default (use simulator)   |
| 81  | Control in place....need to link function calls to Auto Sampler logic.  |
| 82  |   |
| 83  |   |
| 84  |   |
| 85  |   |
| 86  |   |
| 87  |   |
| 88  |   |
| 89  |   |
| 90  | use simulator   |
| 91  |   |
| 92  |   |
| 93  |   |
| 94  |   |
| 95  |   |
| 96  |   |
| 97  | This is referring to the very first design  |
| 98  |   |
| 99  | needs testing with Auto Sampler   |
| 100 |   |
| 101 | needs to be tested with CD4 hardware and algorithm  |
| 102 |   |
| 103 |   |
| 104 | needs testing with auto sampler   |
| 105 | needs testing with auto sampler and CD4.dll   |
| 106 |   |

| A   | B   | C  | D | E      | F |
|-----|-----|--|---|--------|---|
| 113 | 84  | Provide status message after Stat button press. If user presses Stat button again (within time limit) remove request.                              | O |        |   |
| 114 |     | 1 Hide all buttons except "Back" during batch runs and replace with small Carousel ActiveX control.  | O |        |   |
| 115 | 85  | 2 Change "Lymp" label to "Lymph"?  | O |        |   |
| 116 | 86  | The Alert/Flag list boxes need bigger scroll bars for touch screen use, or remove scroll bar and replace with just up/down buttons.                | O |        |   |
| 117 | 87  |  |   |        |   |
| 118 | 88  | <b>CALIBRATION MENU</b>  |   |        |   |
| 119 | 89  | Add "Calibration History" button that will show a table like the Maintenance Log with columns: Parameter, Factor, Target, Status, Date, Time, Mode | O |        |   |
| 120 | 90  | 1 Run button brings up Auto Sampler Screen   | O |        |   |
| 121 |     | Change "Load Diskette" button to "Browse" so user can browse for calibration file.   | O |        |   |
| 122 |     | 1 Need format of calibration file for testing.   | O |        |   |
| 123 |     | 1 Remove "Load Remote" button  | O |        |   |
| 124 | 91  | Add drop down with values 3-8 to specify the number of calibration runs to complete.   | O |        |   |
| 125 | 92  | Calibration samples will be run on auto sampler using logic similar to batch processing (calibration tube put in position 1).                      | O |        |   |
| 126 |     |  |   |        |   |
| 127 |     | <b>CALIBRATION SUMMARY</b>   |   |        |   |
| 128 |     | Add Accept/Reject button to add/remove sample from calculation then automatically recalculate mean and factor values.                              | O |        |   |
| 129 | 93  | 1 A minimum of 3 samples must be accepted for calculation  | O |        |   |
| 130 | 94  |  |   |        |   |
| 131 | 95  | <b>QUALITY CONTROL MENU</b>  |   |        |   |
| 132 | 97  | Add buttons for CD4 Control Menu, CD4 Levy Jennings Chart, CD4 Control Data File   | V | 20-Jan |   |
| 133 |     | A. CD4 Control Menu  |   |        |   |
| 134 | 98  | 1 A maximum of 241 lot #'s can be saved in the table   | V | 20-Jan |   |
| 135 | 99  | 1 Add "Level" column to table  | V | 20-Jan |   |
| 136 | 100 | 1 Make Select/Add/Delete/Edit buttons work for CD4 Controls  | V | 22-Jan |   |
| 137 |     | i. Add CD4 Control Screen  |   |        |   |
| 138 | 101 | 1 Change "Diskette" to "Browse".   | V | 22-Jan |   |
| 139 |     | Modify Control Utility app to include CD4 Control so that CD4 QC range files can be made at PointCare, change DB file to 2000 format               | O |        |   |
| 140 | 102 | 1 Remove "Remote" button   | V |        |   |
| 141 | 103 | ii. Add CD4 Control - Manual Screen  |   |        |   |
| 142 | 104 | 1 Add "Level" field for user to specify low or normal control  | V | 20-Jan |   |
|     |     | Add fields for user to enter ranges on this screen rather than having separate buttons to enter ranges for each level                              | V | 21-Jan |   |
|     |     | 1 Make Save/Clear/Print buttons work for CD4 Controls  | V | 22-Jan |   |
|     |     | B. CD4 Levy-Jennings Chart   |   |        |   |
|     |     | 1 Add "Level" column to Control Selection Table  | V | 27-Jan |   |

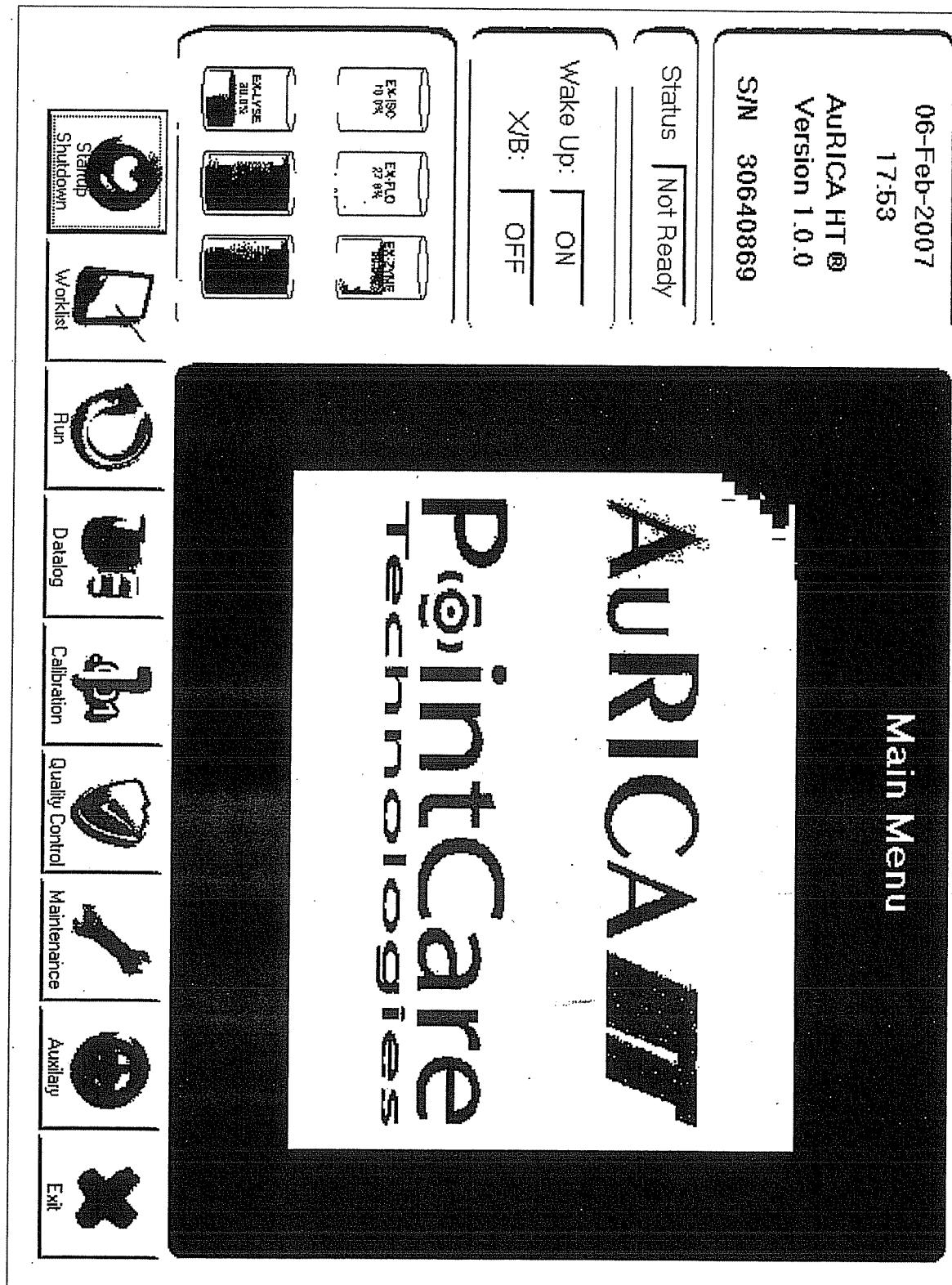
|     |                                     |   |
|-----|-------------------------------------|---|
|     |                                     | G |
| 107 |                                     |   |
| 108 |                                     |   |
| 109 |                                     |   |
| 110 |                                     |   |
| 111 |                                     |   |
| 112 |                                     |   |
| 113 |                                     |   |
| 114 |                                     |   |
| 115 |                                     |   |
| 116 |                                     |   |
| 117 |                                     |   |
| 118 | use calibration/control utility app |   |
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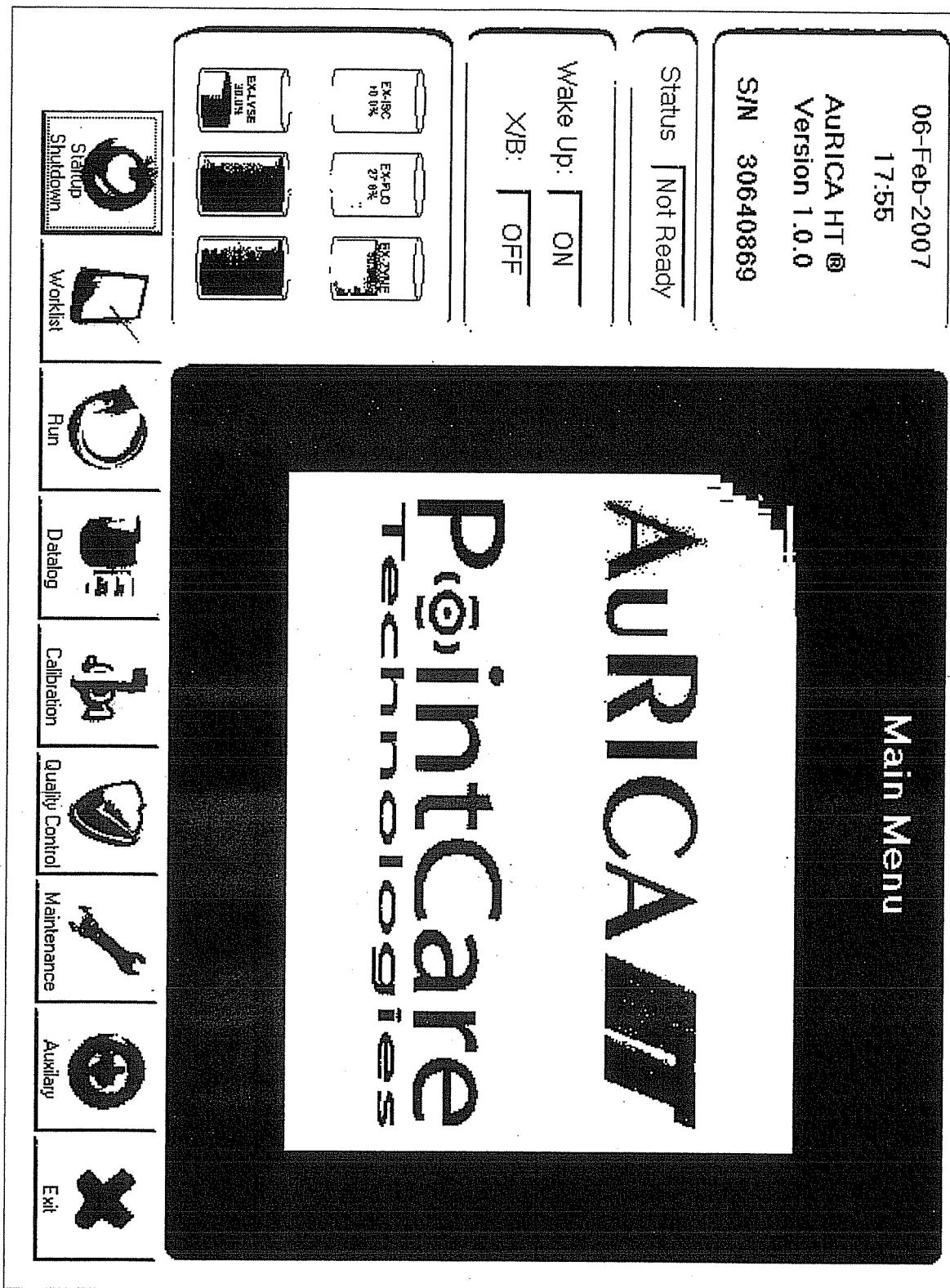
| A   | B   | C  | D   | E | F      |
|-----|-----|--|---|---|--------|
| 143 |     |  | Remove Level buttons and replace with "Select" button for Control Selection   | V | 27-Jan |
| 144 | 105 | 1 Table  | Adjust Control Selection and Month Selection tables so that all column headings are left aligned and all fields are the same width                  | V | 28-Jan |
| 145 | 106 |  | 1 Make Levy-Jennings plot printing work with CD4  | V | 27-Jan |
| 146 | 107 |  | C CD4 Control Data File   | V |        |
| 147 | 108 | 1 Add "Level" column to Control Selection Table  | Remove Level buttons and replace with "Select" button for Control Selection   | V | 28-Jan |
| 148 | 109 | 1 Table  | 1 User to browse to location to save file (default to USB drive)  | V | 28-Jan |
| 149 | 110 | 1 Adjust Control Selection and Month Selection tables so that all column headings are left aligned and all fields are the same width | Under "Review Data", change "Write to Diskette" to "Write to File" and allow Reorder parameter columns in Control Data Files Table to match Datalog | V | 28-Jan |
| 150 | 111 | 1 Make Control Data printing work with CD4   | 1 Make Data Files printing work with CD4  | V | 27-Jan |
| 151 | 112 | 1 Table  | M AINTENANCE MENU   | V | 28-Jan |
| 152 | 113 |  | 1 Move "Sample Status" button to F4 position  | V | 28-Jan |
| 153 | 114 |  | A. Reagents Menu  | O | 23-Jan |
| 154 |     |  | 1 F2 should be "Prime Diluent" button   | V | 28-Jan |
| 155 |     |  | 1 F3 should be "Prime Sheath" button  | V | 28-Jan |
| 156 | 115 |  | 1 F4 should be "Prime Cleaner" button   | V | 28-Jan |
| 157 | 116 | 1 Add CD4 Related Events (Reagents, Controls) to Maintenance Log   | 1 F5 should be "Prime Lys" button   | V | 28-Jan |
| 158 |     |  | 1 F7 should be "Prime Prep" button  | V | 28-Jan |
| 159 |     |  | 1 F8 should be "Replace Reagents" button  | V | 28-Jan |
| 160 |     | i. Replace Reagents Menu   |   |   |        |
| 161 |     | 1 Add two buttons to replace Gold and CD4 Reagents   |   |   |        |
| 162 | 123 | 1 Remove text box for operator initials  |   |   |        |
| 163 | 124 | 1 Support replacement of Gold Kit, Gold Vials (1 or 5 per kit), Prep Kit   |   |   |        |
| 164 | 125 | 1 B. Preventive Maintenance Menu   |   |   |        |
| 165 |     | 3 New Functions TBD  |   |   |        |
| 166 |     | C. Sample Status Screen  |   |   |        |
| 167 |     | 1 Add field for "CD4 OC Count" for 2nd pass total count  |   |   |        |
| 168 | 127 | 1 Add fields for "CD4 Start Rate" and "CD4 End Rate"   |   |   |        |
| 169 | 128 | 1 Modify Sample Status printf function to include new CD4 fields   |   |   |        |
| 170 | 129 | AUXILIARY MENU   |   |   |        |
| 171 |     | 1 Add fields for CD4 and CD4% in Patient & Action Range Screens  |   |   |        |
| 172 | 130 | 1 Fix window pop up when "Printer" button is pressed   |   |   |        |
| 173 | 131 | 1 Add "User Management" button that will bring up the User Manager Screen  |   |   |        |
| 174 | 132 | 1 Implement User Manager utility   |   |   |        |
| 175 |     | A. Advanced Setup  |   |   |        |
| 176 |     | 1 button disabled if user not "Service"  |   |   |        |
| 177 |     | 1 Change Lang button to "Choose Language" drop down menu   |   |   |        |
| 178 |     |  |   |   | 1-Feb  |
| 179 |     |  |   |   | 1-Feb  |
| 180 |     |  |   |   | 6-Feb  |
| 181 | 133 |  |   |   | 6-Feb  |
| 182 | 134 |  |   |   | 6-Nov  |
| 183 | 135 |  |   |   | 2-Feb  |

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| 153 |  |
| 154 |  |
| 155 |  |
| 156 |  |
| 157 | did reagents                           |
| 158 |  |
| 159 | use dummy seq. # for now               |
| 160 | use dummy seq. # for now               |
| 161 | use dummy seq. # for now               |
| 162 | use dummy seq. # for now               |
| 163 | use dummy seq. # for now               |
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| 183 | toggles from English to local language |

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| 208 |      |  |   |   |        |
| 209 |      |  |   |   |        |
| 136 | 1    | Remove "Error Code" column from System Log table on screen   | V |   |        |
|     |      | <b>B. Service Menu</b>   |   |   |        |
| 137 | 1    | button disabled if user not "Service"  | V |   | 30-Nov |
|     | i.   | <b>Operation Setup</b>   |   |   |        |
| 138 | 1    | Remove "Operating Mode" frame  | V |   |        |
| 139 | 1    | Remove "SSD Sampler" option from Misc. frame   | V |   |        |
| 140 | 1    | "CN Free Lysé" option should be true by default  | V |   | 2-Feb  |
| 141 | 1    | Change "Control Mode" frame to "CBC Control Mode"  | V |   | 2-Feb  |
| 142 | 1    | Add "CD4 Control Mode" frame with same 2 fields  | V |   | 2-Feb  |
| 143 | 1    | Add "Display Button Images" checkbox   | V |   | 2-Feb  |
|     | ii.  | <b>Shipping</b>  |   |   |        |
| 144 | 1    | Remove prompt for initials   | V |   |        |
| 145 | 1    | Replace old prompts with new instructions for operation  | H |   |        |
|     | iii. | <b>Constants Setup - Impedance Constants</b>   |   |   |        |
| 146 | 1    | Remove Auto Sampler Constants from screen  | V |   | 2-Feb  |
| 147 | 1    | Move Serial Number to top of screen  | V |   | 2-Feb  |
|     |      | Have "Create Database" button allow user to browse to a location (default: USB drive) to save file     | V |   | 2-Feb  |
| 148 | 1    |  | V |   | 2-Feb  |
|     | iii. | <b>Constants Setup - Special Constants</b>   |   |   |        |
| 149 | 1    | Add new frame called "CD4 Reagent Stability" and add fields for Gold and CD4 Reagents                  | V |   | 2-Feb  |
| 150 | 1    | Add new screen to change CD4 Algorithm Constants   | V |   | 2-Feb  |
|     |      | <b>DATABASE FIXES</b>  |   |   |        |
|     |      | Resolve Patient ID/Sample ID ambiguity when using barcodes (Worklists, Temp Worklist, Datalog tables). | C |   |        |
|     | 151  | Move EOS column to be before BIAS column in master DB to match Datalog table                           | V |   | 30-Oct |
|     | 152  |  |   |   |        |
|     | 153  | Temp Control Table design should match Control Table design in master DB.                              | V |   | 30-Sep |

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| 184 |  |
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| 187 |  |
| 188 |  |
| 189 |  |
| 190 | remove from setup DB, only one type of sampler |
| 191 |  |
| 192 |  |
| 193 |  |
| 194 |  |
| 195 |  |
| 196 |  |
| 197 | New instructions needed?                       |
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| 199 |  |
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| 201 |  |
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| 205 |  |
| 206 |  |
| 207 | needs more testing on instrument               |
| 208 |  |
| 209 |  |





## **EXHIBIT 8**

**From:** Karl Gu  
**Sent:** 2/20/2007 7:20:53 PM  
**To:** Jennifer Waite  
**CC:** Andrea Desrosiers; Dorothy Branco; Don Barry; Andrew Kenney  
**Subject:** RE: CD4 UI and DLL code

Hi Jen,

It seems to me that I would not be able to offer much help for the problems that you are having. I have not downloaded your code yet. My schedule is full this week and I will be out of office next week. Here I will offer a little suggestions and clarify things a little bit if there is any confusion before.

First of all, when you have a problem with VB, VB is complaining something. This only tells you there is a problem. However, the real problem might be something else. What I am trying to say is that carousel ActiveX control probably is not the real problem but CD4 dll is the real problem.

You can create a separate simple VB to talk to CD4 dll. Try one function with no parameter, then add parameter passing, step by step to find what is the problem. There are plenty of book, msdn, internet example around. With the joint effort from you, Andrea, and Dorothy, I am confident that you can solve the problem.

second, if carousel activex control do have a problem, Jason will fix the problem. However, Jason has no responsibility to fix any other piece of code. I asked Capsher last week if they have resource and willing to offer help if PCT request and pay the expense. No response so far. It is very hard to find consultant that only do debugging work.

In summary, if PCT team believes that Jason or me will be responsible for fixing all problems related with code produced by PCT team, this is really an unfortunate confusion. I will offer some help if I am available. Capsher will offer help if they are paid by PCT for their work. I hope this is clear.

BTW, Items other than 1 and 2 are trivial.

Regards,  
Karl

-----Original Message-----

From: Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
Sent: Thu 2/15/2007 6:14 PM  
To: Karl Gu  
Cc: Andrea Desrosiers; Dorothy Branco; Don Barry  
Subject: CD4 UI and DLL code

Hi Karl,

If you go to <ftp://webmail.pointcare.net> and log in with username "drewsci" and password "cowboys" you will see a folder called "15-Feb-07". In there you'll find a zip file for the UI and a zip file for the DLL...as well as my updated To Do list. Dorothy did not include the code for the actual CD4 algorithm...only the framework. Here is a short summary of what is left to be done/fixed...

1. CD4 DLL and UI Integration Issues

The UI is still getting the same error message when trying to call a function from the DLL. The error description is below in the email chain. For you to test these function calls ... copy the Excell24 directory to your C drive. Then, when you start the UI, go into the Datalog and try to view results for sample number 344. Make sure to put the ExcellCD4.dll file into your C:\Windows\System32 folder.

2. Microsoft Visual Basic IDE crashes with CarouselActiveX.ocx

In the code I gave you I removed the reference to the Carousel ActiveX control from the project...as well as commented out all code referring to the control. When this control is part of the VB project... I have trouble compiling, running, or even saving the project without the IDE crashing on me. Try it!

3. Adding CD4 to LIS Communications

Do you have a sample .ORD file you can send me? I assume this file will contain information about the sample type (CBC or CD4)... correct? Do you know how that will appear in the .ORD file?

4. Control Utility App

I need to update this for CD4 Controls.

5. A couple of other small things

See spreadsheet

6. UPS Communications

I haven't had a chance to do this yet

7. Installation

I haven't had a chance to do this yet

Best Regards,

Jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

tel: (508) 281-6926 x15

fax: (508) 281-6930

jwaite@pointcare.net

-----Original Message-----

From: Karl Gu [mailto:kgu@mwi-danam.com]

Sent: Sunday, February 11, 2007 4:04 PM

To: Jennifer Waite

Cc: Andrea Desrosiers; Dorothy Branco

Subject: RE: dll header

Hi Jen,

I am extremely busy recently and may not have any time in two to three days. However, after that I will take a look if you could provide the following:

1. VB code
2. CD4 dll source without the actual algorithm, keep to yourself if you prefer.

Regards,

Karl

-----Original Message-----

From: Jennifer Waite [mailto:jwaite@pointcaretechnologies.com]

Sent: Sat 2/10/2007 11:38 AM

To: Karl Gu

Cc: Andrea Desrosiers; Dorothy Branco

Subject: FW: dll header

Hi Karl,

Dorothy and I are having a bit of trouble integrating her DLL calls into my UI code. I have included (at the bottom of this email) both the VB code declaring and calling the DLL functions as well as Dorothy's VC++ code for exporting the functions. I'm hoping that you can give us some advice since you've done this exact thing before with Hematology.dll. When we started debugging, we were getting the following VB error (from MSDN) at the call to LoadCD4Params():

#### Error in Loading DLL (Error 48)

A dynamic link library (DLL) is a library specified in the Lib clause of a Declare statement. This has the following causes and solutions:

- \* The file isn't DLL-executable.

If the file is a source-text file, it must be compiled and linked to DLL executable form.

- \* The file isn't a Microsoft Windows DLL.

Obtain the Microsoft Windows DLL equivalent of the file.

- \* The file is an early Microsoft Windows DLL that is incompatible with Microsoft Windows protect mode.

Obtain an updated version of the DLL.

- \* The DLL references another DLL that isn't present.

Obtain the referenced DLL and make it available to the other DLL.

- \* The DLL or one of the referenced DLLs isn't in a directory specified by your path.

Move the DLL to a referenced directory or place its current directory on the path.

Dorthy and then changed her code to use the PASCAL EXPORT calls. Now... when the UI calls LoadCD4Params()... the VB IDE crashes completely without giving any intelligent error message. Also... I can't even compile the UI executable without the VB IDE crashing before the compile is complete. (This started happening intermittently ever since I linked in the Carousel ActiveX code.)

Any help or advice you can give us would be great!!  
-Jen

```
|||||||||||||||||||||||||||||||||||||||||  
|||||||||||||||||||||||||||||||||||||  
|
```

#### VB DECLARATIONS (in DllApp.bas):

```
'removed one parameter for easier debug
Public Declare Function LoadCD4Params Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef CD4_Patient_Parms As
CD4_Algorithm_Parameters) As Integer

'original declaration
Public Declare Function LoadCD4Params Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef CD4_Patient_Parms As
CD4_Algorithm_Parameters, ByVal CD4FCSFileId As String) As Integer

Public Declare Function ReadCD4Results Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef WideAngleCD4 As Byte, _
ByRef SmallAngleCD4 As Byte, _
ByRef ExtinctionCD4 As Byte, _
ByRef RightAngleCD4 As Byte, _
ByRef ClassificationCD4 As Byte, _
ByRef CalculatedResultsCD4 As
Calculated_CD4, _
ByVal CD4FCSFileId As String, _
ByVal WBCCount As Long, _
ByVal NeutCount As Long, _
ByVal LYMCount As Long, _
ByVal MonoCount As Long, _
ByVal CBCFlags As Long) As Integer
```

#### VB FUNCTION CALLS (in frmDatalogresult.DisplayResults())

```

Dim i As Integer
If iSampleType = 4 Or iSampleType = 5 Then
If iSampleType = 4 Then
result = LoadCD4Params(CD4_Patient_Params)
'result = LoadCD4Params(CD4_Patient_Params, strCD4FCS)
Else
result = LoadCD4Params(CD4_Control_Params)
'result = LoadCD4Params(CD4_Control_Params, strCD4FCS)
End If

result = ReadCD4Results(WideAngleCD4(0), SmallAngleCD4(0),
ExtinctionCD4(0), _
RightAngleCD4(0), ClassificationCD4(0),

CalculatedResultsCD4, strCD4FCS,
CalculatedResults.result(0), _
CalculatedResults.result(1),
CalculatedResults.result(2), _
CalculatedResults.result(3),
CalculatedResults.Flags)
MergeResults
End If

```

---

From: Dorothy Branco  
 Sent: Fri 2/9/2007 5:03 PM  
 To: Jennifer Waite  
 Subject: dll header

Here's the code in ExcellCD4API.h for exporting the functions from ExcellCD4.dll. The commented code was the original code convention. Then I changed the call to PASCAL EXPORT because of the note about exporting functions to non\_MFC applications from a DLL dynamically linked against the MFC DLLs. I also added "AFX\_MANAGE\_STATE(AfxGetStaticModuleState());" before each export function body in ExcellCD4.cpp.

```

///////////
///////////
/////////
#ifndef _EXCELLCD4_DLL_API_
#define _EXCELLCD4_DLL_API_
#include "SysComns.h"

```

```
extern "C" int PASCAL EXPORT LoadCD4Params(CD4_Algorithm_Parms
*pCD4PatientParams);

extern "C" int PASCAL EXPORT ReadCD4Results(BYTE *pWideAngle,
BYTE *pExtinction,
BYTE *pSmallAngle,
BYTE *pSuperWideAngle,
BYTE *pClassification,
sample *pCalculated,
char *FCSFileName,
long WBCCount,
long NeutCount,
long LymCount,
long MonoCount,
long CBCFlags);

//extern "C" __declspec (dllexport) int ReadCD4Results(BYTE *pWideAngle,
// BYTE *pExtinction,
// BYTE *pSmallAngle,
// BYTE *pSuperWideAngle,
// BYTE *pClassification,
// sample *pCalculated,
// char *FCSFileName,
// long WBCCount,
// long NeutCount,
// long LymCount,
// long MonoCount,
// long CBCFlags);

//extern "C" __declspec (dllexport) int
LoadCD4Params(CD4_Algorithm_Parms *pCD4PatientParams,
//CString FCSFileName);
#endif
///////////
///////////
/////////
```

## **EXHIBIT 9**

**From:** Karl Gu  
**Sent:** 3/5/2007 4:23:07 PM  
**To:** Jennifer Waite  
**CC:** Andrea Desrosiers; Don Barry  
**Subject:** RE: CD4 UI Update

Hi Jen,

Thank you for the update.

Once Capsher sort out the porblem, you may need to come to Dallas to work a few days to finish the integration. For now, I do not need the VB code.

Regards,  
Karl

---

**From:** Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
**Sent:** Monday, March 05, 2007 8:54 AM  
**To:** Karl Gu  
**Cc:** Andrea Desrosiers; Don Barry  
**Subject:** RE: CD4 UI Update

And...here's the spreadsheet! Sorry about that.

Jennifer Waite  
Software Engineer  
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fax: (508) 281-6930  
[jwaite@pointcare.net](mailto:jwaite@pointcare.net)

-----Original Message-----

From: Jennifer Waite  
Sent: Friday, March 02, 2007 6:19 PM

To: Karl Gu'  
Cc: Andrea Desrosiers; Don Barry  
Subject: CD4 UI Update

Hi Karl,

Here is an updated copy of my To-Do list. Most everything is complete....except that we are waiting on Capsher to fix the Carousel ActiveX problem and help us with the CD4 DLL. They've had our code for over a week now and haven't updated me on their progress. I will be giving Kevin Sherry a call on Monday to check on the status. We have been communicating with him directly.

The To-Do spreadsheet includes a sheet that defines changes to the Proprietary Transfer Protocol's data stream...due to the added CD4 information that I have available to me at this time. CD4 flagging has not been defined yet.

Please let me know if you want me to make the VB Source Code available to you via our FTP site.

Best Regards,

Jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

tel: (508) 281-6926 x15

fax: (508) 281-6930

jwaite@pointcare.net

| A  | B   | C  | D           | E      | F             |
|----|---|--|-------------|--------|---------------|
| 1  | AURICA HT User Interface To-Do List - Release 1   |  |             |        |               |
| 2  | Maintained By: Jennifer Waite   |  |             |        |               |
| 3  | Status Codes: Open, Coded, Verified, On Hold  |  |             |        |               |
| 4  | Priority Codes: 1: High, 2: Medium, 3: Low  |  |             |        |               |
| 5  |   |  |             |        |               |
| 6  |   |  |             |        |               |
| 7  | Item  | Priority   | Description | Status | Date Verified |
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| 34 |   |  |             |        |               |
|    | <b>GENERAL</b>  |  |             |        |               |
|    | The screen resolution for the user interface will be kept at 800x600 for Release 1.   | V  |             | 30-Sep |               |
|    | There will be a single executable for the PointCare and Drew user interface for Release 1.  | V  |             | 30-Sep |               |
|    | For CD4 reporting, there will be 2 FCS files created; one for the 1st pass with no gold, one for the 2nd pass with gold.                | C  |             | 30-Sep |               |
|    | Remove option for user to run sample in "Direct Mode" (open tube).  | V  |             | 30-Sep |               |
|    | 1 Make all buttons larger for touch screen use.<br>Use "Back" or up arrow icon instead of "Exit" on all Pg buttons except on Main Menu. | V  |             | 30-Sep |               |
|    | 3 Change all date entry text boxes to drop down menus for localization.   | V  |             | 23-Feb |               |
|    | Remove Worklist and Mode fields from all screens as these are related with Direct Mode sampling.  | V  |             | 30-Sep |               |
|    | 1 Remove Type fields from all screens except the Auto Sampler screen.   | V  |             | 30-Sep |               |
|    | 10  | 1 Change screen layout on non-service screens to use new graphics scheme<br>Image buttons will contain both an image and text. The text will be on the lower portion of the button. Only high level and common buttons will have images. | V           |        | 7-Jan         |
|    | 11  | 1 Make button image display configurable   | C           |        |               |
|    | 12  | 1 Unused buttons will be hidden  | C           |        |               |
|    | 13  | 1 Function keys for buttons will not be supported anymore..  | V           |        | 7-Jan         |
|    | 14  | 1 Tab key should jump through all buttons on screen  | V           |        | 7-Jan         |
|    | 15  | 2 Need to determine when computer is operating off of UPS  | O           |        |               |
|    | 16  | Link in new CD4_all library to call LoadCD4Parameters()  | C           |        |               |
|    | 17  | 1 ReadCD4Results() functions.<br>Need custom pop-up message box that have larger Yes/No/Ok/Cancel buttons for use with touch screen  | C           |        |               |
|    | 18  | 1 Create 3 user levels: Service, Administrator, Technician<br>1 Login Screen will have drop down menu for choosing a user name   | V           |        | 30-Oct        |
|    | 19  | 1 Initial login after install will contain only one user   | H           |        | 6-Feb         |
|    | 20  | 1 "Service" user will have an unchangeable username and password   | V           |        |               |

|    | G  |
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| 4  | 50%  |
| 5  | 6%   |
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| 8  | Notes, Comments, Questions   |
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| 11 |  |
| 12 |  |
| 13 |  |
| 14 |  |
| 15 |  |
| 16 |  |
| 17 | Did all but expiration date text box on frmChangeReagents. This needs to stay a text box for the hand-held barcode reader. |
| 18 |  |
| 19 |  |
| 20 |  |
| 21 | Dennis delivered first set of images on 1/17/07, 2nd set on 2/5/07   |
| 22 |  |
| 23 |  |
| 24 |  |
| 25 |  |
| 26 | UPS just arrived.  |
| 27 | Getting error when calling these functions. Waiting for help from Capster.   |
| 28 | This applies to all forms with small buttons. Hold until after 1st release.  |
| 29 |  |
| 30 |  |
| 31 |  |
| 32 |  |
| 33 | Final Excel24.mdb will have only "Service" user in database when installed.  |
| 34 | need Encryption utility to encrypt/decrypt passwords   |

| A  | B | C       | D  | E | F      |
|----|---|---------|--|---|--------|
| 35 |   | 23<br>1 | "Service" user can create multiple Technician and Administrator users and change their passwords.  | V | 6-Feb  |
| 36 |   | 24<br>1 | "Administrator" user can create multiple Technician users and change their passwords.  | V | 6-Feb  |
| 37 |   | 25<br>1 | All prompts for operator initials need to be removed because operator username will be used.   | V | 30-Oct |
| 38 |   | 26<br>1 | Replace reagent consumption progress bars with new ActiveX control   | V |        |
| 39 |   |         | <b>MAIN MENU</b>   |   |        |
| 40 |   | 27<br>1 | Add 2 progress bars for monitoring Gold and CD4 Reagent fluid levels.  | V | 30-Sep |
| 41 |   | 28<br>1 | Run button brings up Auto Sampler Screen instead of Run Menu Screen. Autosampler status must be queried before the Autosampler Run Screen is showed.   | V | 30-Oct |
| 42 |   | 29<br>1 | Calibration button grayed if user is Technician  | C |        |
| 43 |   | 30<br>1 | <b>STARTUP AND SHUTDOWN MENU</b>   |   |        |
| 44 |   | 31<br>1 | Add 2 progress bars for monitoring Gold and CD4 Reagent fluid levels.  | V | 30-Sep |
| 45 |   | 32<br>1 | Add "Logout" button which will bring up the login screen   | V | 30-Oct |
| 46 |   | 33<br>1 | After shutdown sequence is completed, bring up the login screen.   | V | 30-Oct |
| 47 |   | 34<br>1 | "Wake Up" function runs Startup behind the scenes to put instrument in Ready state. Once user logs back in, the instrument is ready to perform a test.   | C |        |
| 48 |   | 35<br>1 | User can log out without running a shutdown. The auto shutdown will start at scheduled time.   | C |        |
| 49 |   |         | <b>WORKLIST MENU</b>   |   |        |
| 50 |   | 36<br>1 | <b>A. Edit Worklist</b><br>Remove "Add Sample" Button  | V | 30-Nov |
| 51 |   |         | Reorder remaining buttons; Add Sample Carousel 1, Add Sample Carousel 2, Add Sample Carousel 3, Revise Selection, Delete Selection   | V | 30-Nov |
| 52 |   | 37<br>1 | Add column for "Collection Time" in Worklist table and Temp Worklist table   | V | 30-Nov |
| 53 |   | 38<br>1 | Change Print function to account for new fields in Worklist table.   | V | 9-Jan  |
| 54 |   | 39<br>1 | <b>B. Add Carousel 1/2/3 Menu</b>  |   |        |
| 55 |   | 40<br>1 | Add "Sample Collection Time" field (not mandatory field)<br>Add "CD4 Max Age" parameter to setup database and add field on Special Constants screen to edit parameter  | V | 30-Nov |
| 56 |   | 41<br>1 | When user enters collection time, check to be sure cbc sample is less than 8 hours old and cd4 sample is less than "CD4 Max Age". Ask user for confirmation before proceeding if sample too old. If told to proceed, set "CBC Sample Age" and/or "CD4 Sample Age" alerts | V | 7-Feb  |
| 57 |   | 42<br>1 | Add radio buttons for "CBC only" and "CBC with CD4", default = "CBC with CD4".   | V | 9-Feb  |
| 58 |   | 43<br>1 | Remove Male/Female buttons and add Gender drop down list with values: Male, Female, Unspecified  | V | 30-Nov |
| 59 |   | 44<br>1 | Add buttons for CD4 Low Control and CD4 Normal Control   | V | 30-Nov |
| 60 |   | 45<br>1 |  |   |        |

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| 40 |                                      |   |
| 41 |                                      |   |
| 42 |                                      |   |
| 43 | Needs to be verified on hardware     |   |
| 44 |                                      |   |
| 45 |                                      |   |
| 46 |                                      |   |
| 47 |                                      |   |
| 48 |                                      |   |
| 49 |                                      |   |
| 50 | Needs to be verified on hardware     |   |
| 51 | Needs to be verified on hardware     |   |
| 52 |                                      |   |
| 53 |                                      |   |
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| 61 |                                      |   |
| 62 |                                      |   |
| 63 |                                      |   |
| 64 | Using blank instead of "Unspecified" |   |
| 65 |                                      |   |

| A  | B | C  | D | E | F      |
|----|---|--|---|---|--------|
| 66 |   | Reorder buttons; Find Match by Patient ID, Find Match by Name, Low Control, Normal Control, High Control, CD4 Low Control, CD4 Normal Control, Save, Exit. | V |   | 30-Nov |
| 67 |   | <b>C. Revise Selection Menu</b>  | V |   | 30-Nov |
| 68 |   | 1 Add "Sample Collection Time" field (not mandatory field)   | V |   | 30-Sep |
| 69 |   | Add radio buttons for "CBC only" and "CBC with CD4", default = "CBC with CD4".   | V |   | 30-Nov |
| 70 |   | Remove Male/Female buttons and add Gender drop down list with values: 1 Male, Female, Unspecified  | V |   | 30-Nov |
| 71 |   | 1 Add buttons for CD4 Low Control and CD4 Normal Control   | V |   | 30-Nov |
| 72 |   | Reorder buttons: Find Match by Patient ID, Find Match by Name, Low Control, Normal Control, High Control, CD4 Low Control, CD4 Normal Control, Save, Exit. | V |   | 30-Nov |
| 73 |   |  |   |   |        |
| 74 |   | <b>AUTO SAMPLER RUN MENU</b>   | V |   | 30-Oct |
| 75 |   | 1 Apply new screen layout with button images designed by Dennis  | V |   | 30-Oct |
| 76 |   | 1 Add progress bars for monitoring all reagent fluid levels  | V |   | 30-Oct |
| 77 |   | 1 Keep "Type" field to differentiate between Patient and Control samples.  | V |   | 30-Oct |
| 78 |   | 1 Add "Run Background" button  | C |   |        |
| 79 |   | Define and support reading new barcode formats for CD4 Controls and CD4 Patient Samples  | C |   |        |
| 80 |   | 1 Patient Samples  | V |   | 30-Oct |
| 81 |   | 1 Remove "Stat Direct" and "Stat Save" buttons.  | C |   |        |
| 82 |   | 1 By default, run is CD4   | O |   |        |
| 83 |   | 3 LIS query. If no sample type returned, use default specified by UI.  |   |   |        |
| 84 |   | Incorporate new Carousel ActiveX control in screen and function calls into Auto Sampler logic  | H |   |        |
| 85 |   | 1 Group date, instrument, S/N into one green box   | V |   | 3-Jan  |
| 86 |   | 1 Group wake up status and X/B status into one green box   | V |   | 3-Jan  |
| 87 |   | 1 Change Analyzer Status back to text box, not light images  | V |   | 3-Jan  |
| 88 |   | After tubes are mapped, before starting the batch, user may click tube cap on 1 carousel control to toggle patient sample type between CBC and CD4.        | H |   | 2-Mar  |
| 89 |   | <b>DATALOG MENU</b>  |   |   |        |
| 90 |   | 1 Add CD4# and CD4% parameters to Datalog Table (Insert after Bas param)   | V |   | 30-Sep |
| 91 |   | 1 Move Bas after Eos and Bas% after Eos% in Datalog Table  | V |   | 30-Sep |
| 92 |   | Unsupported params will show up as blank in the Datalog table and will be blank in the database  | V |   | 9-Jan  |
| 93 |   | 1 Add CD4# and CD4% parameters to data stream for Transfer function  | C |   |        |
| 66 |   |  |   |   |        |

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| 66 |   |
| 67 |   |
| 68 |   |
| 69 |   |
| 70 | Using blank instead of "Unspecified"  |
| 71 |   |
| 72 |   |
| 73 |   |
| 74 |   |
| 75 |   |
| 76 |   |
| 77 |   |
| 78 | Needs to be run on hardware   |
| 79 | Needs to be run on hardware   |
| 80 |   |
| 81 | Works graphically, but needs testing with Auto Sampler  |
| 82 | Need example of .ORD file (created by ExcelLis.dll) with test type information included. Will Collection Time be included in order file?  |
| 83 | Function calls exist and are commented out. Will uncomment when Capster fixes bug. (IDE crashes when including Carousel ActiveX as a reference in project)  |
| 84 |   |
| 85 |   |
| 86 | Function calls exist and are commented out. Will uncomment when Capster fixes bug. (IDE crashes when including Carousel ActiveX as a reference in project)  |
| 87 |   |
| 88 |   |
| 89 |   |
| 90 |   |
| 91 |   |
| 92 | Is it necessary for VB to differentiate between CBC Control and CD4 Control in .RE (results) file? If so...how? Should Collection Time (and sample age alert?) be transferred under all 3 modes? If so...how? See sheet entitled "New Proprietary Xfer Format" for changes to Proprietary Protocol's data transmission format. Use simulator for testing. |
| 93 |   |

| A   | B | C  | D  | E | F      |
|-----|---|----|--|---|--------|
| 94  |   | 67 | 1 Add CD4# and CD4% to all printouts   | V | 15-Jan |
| 95  |   | 68 | 1 Add CD4# and CD4% to statistic calculations  | V | 12-Jan |
| 96  |   | 69 | 1 Add "Find Date" button to allow user to search by a date   | V | 12-Jan |
| 97  |   | 70 | 1 Do not change Datalog table cell heights if user clicks "Change" button  | V | 9-Jan  |
| 98  |   | 71 | 1 Add column for "Collection Time" to Datalog Table<br><br>If user edits collection time, check to be sure cbc sample is less than 8 hours old and cd4 sample is less than "CD4 Max Age". Ask user for confirmation before proceeding if sample too old. If told to proceed, set "CBC Sample Age" and/or "CD4 Sample Age" alerts | V | 7-Feb  |
| 99  |   | 72 | 1 Add radio buttons or drop down menu to switch 3-D plot between CBC and CD4 plot.   | V | 9-Feb  |
| 100 |   | 73 | 1 Apply new screen layout with button Images designed by Dennis  | V |        |
| 102 |   | 73 | Keep Datalog Results display and Auto Sampler Results display in separate VB forms   | V |        |
| 103 |   | 74 | 1 Add "Previous" and "Next" buttons to Auto Sampler Results screen to scroll through results for current batch.  | C |        |
| 104 |   | 75 | 1 Add CD4# and CD4% result fields, keep blank for CBC only   | C |        |
| 105 |   | 76 | 1 Add radio buttons or drop down menu to switch 3-D plot between CBC and CD4 plot.   | C |        |
| 106 |   | 77 | 1 Add CD4 results to printout  | V |        |
| 107 |   | 78 | 1 Include "Collection Time" and Sample Age alerts on result full printout (datalog results and asterisks)  | V | 9-Feb  |
| 108 |   | 79 | 1 If CD4 run, show 2-D CD4 plot instead of 2-D Eos plot in printout  | C |        |
| 109 |   | 80 | 1 Add "Edit Comments" button to AutoSampler result form  | C |        |
| 110 |   | 81 | 1 Create 2D CD4 plot   | C |        |
| 111 |   | 82 | 1 Remove animation   | V |        |
| 112 |   | 83 | Provide status message after Stat button press. If user presses Stat button again (within time limit), remove request  | C |        |
| 113 |   | 84 | 1 Hide all buttons except "Back" during batch runs and replace with small Carousel ActiveX control.  | H |        |
| 114 |   | 85 | 3 Change "Lymph" label to "Lymph"?   | H |        |
| 115 |   | 86 | The AlertFlag list boxes need bigger scroll bars for touch screen use, or remove scroll bar and replace with just up/down buttons.   | H |        |
| 116 |   | 87 |  |   |        |
| 117 |   |    |  |   |        |
| 118 |   |    |  |   |        |
| 119 |   | 88 | Add "Calibration History" button that will show a table like the Maintenance Log with columns: Parameter, Factor, Target, Status, Date, Time, Mode   | V | 11-Feb |
| 120 |   |    |  |   |        |
| 121 |   |    |  |   |        |
| 122 |   | 89 | 1 Run button brings up Auto Sampler Screen   | V | 12-Feb |
| 123 |   | 90 | Change "Load Diskette" button to "Browse" so user can browse for calibration file.   | V | 12-Feb |
| 124 |   | 91 | 1 Remove "Load Remote" button  | V | 12-Feb |
| 125 |   | 92 | 1 Add drop down with values 3-8 to specify the number of calibration runs to complete.   | V | 12-Feb |

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| 99  |  |
| 100 |  |
| 101 |  |
| 102 | This is referring to the very first design.  |
| 103 |  |
| 104 | needs testing with Auto Sampler  |
| 105 |  |
| 106 | needs to be tested with CD4 hardware and algorithm   |
| 107 |  |
| 108 |  |
| 109 |  |
| 110 | needs testing with auto sampler  |
| 111 | needs testing with auto sampler and CD4.dll  |
| 112 |  |
| 113 | needs testing with hardware  |
| 114 | Function calls exist and are commented out. Will uncomment when Capster fixes bug. (IDE crashes when including Carousel ActiveX as a reference in project) |
| 115 | Not necessary for 1st release.   |
| 116 | Not necessary for 1st release.   |
| 117 |  |
| 118 |  |
| 119 |  |
| 120 |  |
| 121 |  |
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| A   | B   | C  | D | E      | F |
|-----|-----|--|---|--------|---|
| 126 | 93  | Calibration samples will be run on auto sampler using logic similar to batch processing (calibration tube put in position 1)                       | C |        |   |
| 127 |     |  |   |        |   |
| 128 |     |  |   |        |   |
| 129 | 94  | <b>CALIBRATION SUMMARY</b><br>Add Accept/Reject button to add/remove sample from calculation then automatically recalculate mean and factor values | V | 13-Feb |   |
| 130 | 95  | 1 A minimum of 3 samples must be accepted for calculation  | V | 13-Feb |   |
| 131 |     |  |   |        |   |
| 132 |     | <b>QUALITY CONTROL MENU</b><br>Add buttons for CD4 Control Menu, CD4 Levy Jennings Chart, CD4 Control Data File                                    | V | 20-Jan |   |
| 133 | 96  | <b>A. CD4 Control Menu</b>   |   |        |   |
| 134 |     |  |   |        |   |
| 135 | 97  | 1 A maximum of 24 of #'s can be saved in the table   | V | 20-Jan |   |
| 136 | 98  | 1 Add "Level" column to table  | V | 20-Jan |   |
| 137 | 97  | 1 Make Select/Add/Delete/Edit buttons work for CD4 Controls  | V | 22-Jan |   |
| 138 |     | <b>i. Add CD4 Control Screen</b>   |   |        |   |
| 139 | 99  | 1 Change "Diskette" to "Browse".   | V | 22-Jan |   |
| 140 | 99  | 1 Modify Control Utility app to include CD4 Control so that CD4 QC range files can be made at PointCare, change DB file to 2000 format             | V | 27-Feb |   |
| 141 | 100 | 1 Remove "Remote" button   | V |        |   |
| 142 |     | <b>ii. Add CD4 Control - Manual Screen</b>   |   |        |   |
| 143 | 101 | 1 Add "Level" field for user to specify low or normal control  | V | 20-Jan |   |
| 144 | 102 | 1 Add fields for user to enter ranges on this screen rather than having separate buttons to enter ranges for each level                            | V | 21-Jan |   |
| 145 | 103 | 1 Make Save/Clear/Print buttons work for CD4 Controls  | V | 22-Jan |   |
| 146 |     | <b>B. CD4 Levy-Jennings Chart</b>  |   |        |   |
| 147 | 104 | 1 Add "Level" column to Control Selection Table  | V | 27-Jan |   |
| 148 | 105 | 1 Remove Level buttons and replace with "Select" button for Control Selection Table  | V | 27-Jan |   |
| 149 | 106 | 1 Adjust Control Selection and Month Selection tables so that all column headings are left aligned and all fields are the same width               | V | 28-Jan |   |
| 150 | 107 | 1 Make Levy-Jennings plot printing work with CD4   | V | 27-Jan |   |
| 151 |     | <b>C. CD4 Control Data File</b>  |   |        |   |
| 152 | 108 | 1 Add "Level" column to Control Selection Table  | V | 28-Jan |   |
| 153 | 109 | 1 Remove Level buttons and replace with "Select" button for Control Selection Table  | V | 28-Jan |   |
| 154 | 110 | 1 Adjust Control Selection and Month Selection tables so that all column headings are left aligned and all fields are the same width               | V | 28-Jan |   |
| 155 | 111 | 1 Under "Review Data", change "Write to Diskette" to "Write to File" and allow user to browse to location to save file (default to USB drive)      | V | 28-Jan |   |
| 156 | 112 | 1 Reorder parameter columns in Control Data Files Table to match Datalog Table   | V | 28-Jan |   |
| 157 | 113 | 1 Make Control Data printing work with CD4   | V | 27-Jan |   |
| 158 | 114 | 1 Make Data Files printing work with CD4   | V | 28-Jan |   |
| 159 |     | <b>Maintenance MENU</b>  |   |        |   |
| 160 | 115 | 1 Move "Sample Status" button to F4 position   | V | 23-Jan |   |
| 161 | 116 | 1 Add CD4 Related Events (Reagents, Controls) to Maintenance Log   | C |        |   |

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|     |                     | G |
| 126 | needs testing on hw |   |
| 127 |                     |   |
| 128 |                     |   |
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| 130 |                     |   |
| 131 |                     |   |
| 132 |                     |   |
| 133 |                     |   |
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| A   | B | C  | D | E | F      |
|-----|---|--|---|---|--------|
| 163 |   | <b>A. Reagents Menu</b>  |   |   |        |
| 164 |   | 1 F2 should be "Prime Diluent" button  | V |   | 20-Jan |
| 165 |   | 1 F3 should be "Prime Sheath" button   | V |   | 20-Jan |
| 166 |   | 1 F4 should be "Prime Cleaner" button  | V |   | 20-Jan |
| 167 |   | 1 F5 should be "Prime Lysé" button   | V |   | 20-Jan |
| 168 |   | 1 F7 should be "Prime Prep" button   | V |   | 20-Jan |
| 169 |   | 1 F8 should be "Replace Reagents" button   | V |   | 20-Jan |
| 170 |   | i. Replace Reagents Menu   |   |   |        |
| 171 |   | 1 Add two buttons to replace Gold and CD4 Reagents   | V |   |        |
| 172 |   | 1 Remove text box for operator initials  | V |   | 20-Jan |
| 173 |   | 1 Support replacement of Gold Kit, Gold Vials (1 or 5 per kit), Prep Kit                             | V |   | 20-Jan |
| 174 |   | <b>B. Preventive Maintenance Menu</b>  |   |   |        |
| 175 |   | 3 New Functions TBD  | H |   |        |
| 176 |   | <b>C. Sample Status Screen</b>   |   |   |        |
| 177 |   | 1 Add field for "CD4 OC Count" for 2nd pass total count  | V |   | 1-Feb  |
| 178 |   | 1 Add fields for "CD4 Start Rate" and "CD4 End Rate"   | V |   | 1-Feb  |
| 179 |   | 1 Modify Sample Status print function to include new CD4 fields                                      | V |   | 1-Feb  |
| 180 |   | <b>AUXILIARY MENU</b>  |   |   |        |
| 181 |   | <b>D. Sample Status Screen</b>   |   |   |        |
| 182 |   | 1 Add fields for CD4 and CD4% in Patient & Action Range Screens                                      | V |   | 1-Feb  |
| 183 |   | 1 Fix window pop up when "Printer" button is pressed   | V |   | 1-Feb  |
| 184 |   | 1 Add "User Management" button that will bring up the User Manager Screen                            | V |   | 6-Feb  |
| 185 |   | 1 Implement User Manager utility   | V |   | 6-Feb  |
| 186 |   | <b>A. Advanced Setup</b>   |   |   |        |
| 187 |   | 1 button disabled if user not "Service"  | V |   | 30-Nov |
| 188 |   | 1 Change Lang button to "Choose Language" drop down menu   | V |   | 2-Feb  |
| 189 |   | 1 Remove "Error Code" column from System Log table on screen   | V |   | 2-Feb  |
| 190 |   | <b>B. Service Menu</b>   |   |   |        |
| 191 |   | <b>i. Operation Setup</b>  |   |   |        |
| 192 |   | 1 button disabled if user not "Service"  | V |   | 30-Nov |
| 193 |   | <b>ii. Shipping</b>  |   |   |        |
| 194 |   | 1 Remove "Operating Mode" frame  | V |   |        |
| 195 |   | 1 Remove "SSD Sampling" option from Misc. frame  | V |   |        |
| 196 |   | 1 "CN Free Lysé" option should be true by default  | V |   | 2-Feb  |
| 197 |   | 1 Change "Control Mode" frame to "CBC Control Mode"  | V |   | 2-Feb  |
| 198 |   | 1 Add "CD4 Control Mode" frame with same 2 fields  | V |   | 2-Feb  |
| 199 |   | 1 Add "Display Button Images" checkbox   | V |   | 2-Feb  |
| 200 |   | <b>iii. Constants Setup - Impedance Constants</b>  |   |   |        |
| 201 |   | 1 Remove prompt for initials   | V |   |        |
| 202 |   | 1 Replace old prompts with new instructions for operation  | H |   |        |
| 203 |   | 1 Remove Auto Sampler Constants from screen  | V |   | 2-Feb  |
| 204 |   | 1 Move Serial Number to top of screen  | V |   | 2-Feb  |
| 205 |   | 1 Have "Create Database" button allow user to browse to a location (default: USB drive) to save file | V |   | 2-Feb  |
| 206 |   | 1 iii. Constants Setup - Special Constants   | V |   | 2-Feb  |
| 207 |   |  |   |   |        |

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|     |  | G |
| 163 | use dummy seq. # for now                       |   |
| 164 | use dummy seq. # for now                       |   |
| 165 | use dummy seq. # for now                       |   |
| 166 | use dummy seq. # for now                       |   |
| 167 | use dummy seq. # for now                       |   |
| 168 | use dummy seq. # for now                       |   |
| 169 |  |   |
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| 183 |  |   |
| 184 |  |   |
| 185 |  |   |
| 186 |  |   |
| 187 |  |   |
| 188 | toggles from English to local language         |   |
| 189 |  |   |
| 190 |  |   |
| 191 |  |   |
| 192 |  |   |
| 193 |  |   |
| 194 |  |   |
| 195 | remove from setup DB, only one type of sampler |   |
| 196 |  |   |
| 197 |  |   |
| 198 |  |   |
| 199 |  |   |
| 200 |  |   |
| 201 |  |   |
| 202 | New instructions needed?                       |   |
| 203 |  |   |
| 204 |  |   |
| 205 |  |   |
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| 207 |  |   |

| A   | B | C   | D  | E | F      |
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| 208 |   |     | Add new frame called "CD4 Reagent Stability" and add fields for Gold and CD4 Reagents  | V | 2-Feb  |
| 209 |   | 149 | 1  | V | 5-Feb  |
| 210 |   | 150 | Add new screen to change CD4 Algorithm Constants   |   |        |
| 211 |   |     |  |   |        |
| 212 |   |     |  |   |        |
| 213 |   | 151 | <b>DATABASE FIXES</b><br>Resolve Patient ID/Sample ID ambiguity when using barcodes (Worklist, Temp Worklist, Datalog tables). | C |        |
| 214 |   | 152 | Move EOS column to be before EAS column in master DB to match Datalog table  | V | 30-Oct |
|     |   | 153 | 1 Temp Control Table design should match Control Table design in master DB.  | V | 30-Sep |

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|-----|----------------------------------|
|     | G                                |
| 208 |                                  |
| 209 |                                  |
| 210 |                                  |
| 211 |                                  |
| 212 | needs more testing on instrument |
| 213 |                                  |
| 214 |                                  |

|    | A   | B                                   | C                                 | D              |
|----|---|-------------------------------------|-----------------------------------|----------------|
| 1  | New Format for Proprietary Protocol's Data Transmission |                                     |                                   |                |
| 2  | Red text indicates fields that have changed.            |                                     |                                   |                |
| 3  | BYTE  |                                     |                                   |                |
| 4  |   | FORMAT                              |                                   |                |
| 1  |   | A: ASCII Format<br>B: Binary Format |                                   |                |
| 5  | 2-7   | B1                                  | STX(02h)                          | Jen's Comments |
| 6  | 8-22  | A6                                  | Sequence Number                   |                |
| 7  | 23-37   | A15                                 | Sample Id                         |                |
| 8  | 38-67   | A15                                 | Patient Id                        |                |
| 9  | 68-82   | A30                                 | Last Name                         |                |
| 10 | 83-92   | A15                                 | First Name                        |                |
| 11 | 93  | A10                                 | Birth Date                        |                |
| 12 | 94-123  | A1                                  | Sex (1=Male, 2=Female, 0=Unknown) |                |
| 13 | 124   | A30                                 | Doctor                            |                |
| 14 | 125   | A1                                  | 1=WBC Clog                        |                |
| 15 | 126   | A1                                  | 1=RBC Clog                        |                |
| 16 | 127   | A1                                  | 1=WBC Flow Time                   |                |
| 17 | 128   | A1                                  | 1=RBC Flow Time                   |                |
| 18 | 129   | A1                                  | 1=RBC Drain                       |                |
| 19 | 130   | A1                                  | 1=Vacuum Failure                  |                |
| 20 | 131   | A1                                  | 1=Hgb Sensor                      |                |
| 21 | 132   | A1                                  | 1=Uncontrolled                    |                |
| 22 | 133   | A1                                  | 1=Uncalibrated                    |                |
| 23 | 134-143   | A10                                 | Date(DD/MM/YYYY)                  |                |
| 24 | 144-154   | A11                                 | Time(HH:MM:SS AM/PM)              |                |
| 25 | 155-159   | A5                                  | WBC                               |                |
| 26 | 160-164   | A5                                  | NEUT N                            |                |
| 27 | 165-169   | A5                                  | LYM N                             |                |
| 28 | 170-174   | A5                                  | MONO N                            |                |
| 29 | 175-179   | A5                                  | EOS N                             |                |
| 30 | 180-184   | A5                                  | BAS N                             |                |
| 31 | 185-189   | A5                                  | CD4 N                             |                |
| 32 | 190-194   | A5                                  | NEUT P                            |                |
| 33 | 195-199   | A5                                  | LYM P                             |                |
| 34 | 200-204   | A5                                  | MONO P                            |                |
| 35 | 205-209   | A5                                  | EOS P                             |                |
| 36 | 210-214   | A5                                  | BAS P                             |                |
| 37 | 215-219   | A5                                  | CD4 P                             |                |
| 38 | 220-224   | A5                                  | RBC                               |                |
| 39 | 225-229   | A5                                  | HGB                               |                |
| 40 | 230-234   | A5                                  | HCT                               |                |
| 41 | 235-239   | A5                                  | MCV                               |                |
| 42 | 240-244   | A5                                  | MCH                               |                |
| 43 | 245-249   | A5                                  | MCHC                              |                |
| 44 | 250-254   | A5                                  | RDW                               |                |
| 45 | 255-259   | A5                                  | PLT                               |                |
| 46 | 260-264   | A5                                  | MPV                               |                |

|    | A       | B   | C   | D                     |  |
|----|---------|-----|---|-----------------------|--|
| 47 | 265-269 | A5  | PCT   |                       |  |
| 48 | 270-274 | A5  | PDW   |                       |  |
| 49 | 275-299 | A25 | Reserved for future parameter expansion   |                       |  |
| 50 | 300     | A1  | 1=Diff Flag   |                       |  |
| 51 | 301     | A1  | 1=NBC Flag  |                       |  |
| 52 | 302     | A1  | 1=N Flag  |                       |  |
| 53 | 303     | A1  | 1=B Flag  |                       |  |
| 54 | 304     | A1  | 1=L Flag  |                       |  |
| 55 | 305     | A1  | 1=RBC Abn Flag  |                       |  |
| 56 | 306     | A1  | 1=PLCI Flag   |                       |  |
| 57 | 307     | A1  | 1=PLTRBC Flag   |                       |  |
| 58 | 308-317 | A10 | Future Flag Expansion   | CD4 Flags can go here |  |
| 59 | 318     | A1  | Sample Type:<br>1=Patient (CBC)<br>2=Background<br>3=Calibration<br>4=CBC Low Control<br>5=CBC Normal Control<br>6=CBC High Control<br>7=CD4 Patient<br>8=CD4 Control Low<br>9=CD4 Control Normal |                       |  |
| 60 | 319     | A1  | Sample Mode:<br>1=Direct<br>2=Cap Piercer<br>3=Sampler Saver<br>4=Auto Sampler  |                       |  |
| 61 | 320-325 | A6  | RBC Raw Count   |                       |  |
| 62 | 326-331 | A6  | RBC Tof   |                       |  |
| 63 | 332-337 | A6  | RBC Start Aperture Voltage  |                       |  |
| 64 | 338-343 | A6  | RBC End Aperture Voltage  |                       |  |
| 65 | 344-349 | A6  | PLT Raw Count   |                       |  |
| 66 | 350-355 | A6  | WBC Raw Count   |                       |  |
| 67 | 356-361 | A6  | WBC Tof   |                       |  |
| 68 | 362-367 | A6  | WBC Start Aperture Voltage  |                       |  |
| 69 | 368-373 | A6  | WBC End Aperture Voltage  |                       |  |
| 70 | 374-379 | A6  | HGB Sample  |                       |  |
| 71 | 380-385 | A6  | HGB Reference   |                       |  |
| 72 | 386-391 | A6  | WOC Count   |                       |  |
| 73 | 392-397 | A6  | WOC Start Rate  |                       |  |
| 74 | 398-403 | A6  | WOC End Rate  |                       |  |
| 75 | 404-409 | A6  | Vacuum During Sample  |                       |  |
| 76 | 410     | A1  | 1=CBC Sample Age Alert  |                       |  |
| 77 | 411     | A1  | 1=CD4 Sample Age Alert  |                       |  |
| 78 | 412-417 | A6  | CD4 Optical Count   |                       |  |
| 79 | 418-423 | A6  | CD4 OC Start Rate   |                       |  |
| 80 | 424-429 | A6  | CD4 OC End Rate   |                       |  |

|    |         |   |     |                    |   |
|----|---------|---|-----|--------------------|---|
|    |         | A | B   | C                  | D |
| 81 | 430-453 |   | A24 | Open for expansion |   |
| 82 | 454-455 |   | A2  | Reserved           |   |
| 83 | 456     |   | B1  | EOT(04h)           |   |

**EXHIBIT 10**

**From:** Karl Gu  
**Sent:** 3/26/2007 10:43:19 PM  
**To:** Andrew Kenney; Doug Nickols; Gary Young  
**CC:**  
**Subject:** FW: Project settings for creating a DLL in MSVS

Hi,

See the attached email from Pointcare. Capsher fixed the problem and it is down to Pointcare to supply a version of CD4 dll to go with the unit.

Regards,  
Karl

---

**From:** Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
**Sent:** Monday, March 26, 2007 4:33 PM  
**To:** Kevin Sherry  
**Cc:** Dorothy Branco; Andrea Desrosiers; Karl Gu  
**Subject:** RE: Project settings for creating a DLL in MSVS

Kevin,

Changing those settings seemed to fix our initial problem when calling the DLL. We have more work to do to fix the meat of the DLL functions... but we now on our way! I also have experience no crashes since you sent the new Carousel .ocx file. Thanks again!

-Jen

Jennifer Waite  
Software Engineer  
PointCare Technologies, Inc.  
tel: (508) 281-6926 x15  
fax: (508) 281-6930

jwaite@pointcare.net

-----Original Message-----

From: Kevin Sherry [mailto:[sherry@capsher.com](mailto:sherry@capsher.com)]  
Sent: Friday, March 23, 2007 4:23 PM  
To: Jennifer Waite  
Subject: Project settings for creating a DLL in MSVS

Hi Jennifer,

Upon further inspection of the project you sent me, it looks like the Release mode settings were configured to build an EXE file, while the Debug settings were configured to build a DLL file.

I think you want both Release and Debug modes to create the same type of file (DLL), so here are instructions for setting up both modes.

To create a DLL in Release mode:

- 
1. Go to Project\Settings dialog
  2. Select "Win32 Release" from the "Settings For:" drop-down list
  3. Click on the "Link" property page
  4. Copy the following line of settings

/nologo /subsystem:windows /dll /incremental:no /pdb:"Release/ExcelCD4.pdb" /machine:I386  
/def:".\\ExcelCD4.def" /out:"Release/ExcelCD4.dll" /implib:"Release/ExcelCD4.lib"

5. Paste into the multi-line edit called "Project Options:" at the bottom of the "Link" property page. Make sure you overwrite completely whatever was in the edit before.

6. Hit OK

To create a DLL in Debug mode:

---

1. Go to Project\Settings dialog
2. Select "Win32 Debug" from the "Settings For:" drop-down list
3. Click on the "Link" property page
4. Copy the following line of settings

```
/nologo /subsystem:windows /dll /incremental:yes /pdb:"Debug/ExcellCD4.pdb" /debug  
/machine:I386 /def:".\\ExcellCD4.def" /out:"Debug/ExcellCD4.dll" /implib:"Debug/ExcellCD4.lib"  
/pdbtype:sept
```

5. Paste into the multi-line edit called "Project Options:" at the bottom of the "Link" property page. Make sure you overwrite completely whatever was in the edit before.

6. Hit OK

Let me know if this helps.

Best Regards,

Kevin

Kevin Sherry

<mailto:sherry@capsher.com>

CAPSHER TECHNOLOGY, INC.

2402 BROADMOOR DR STE A204

BRYAN, TX 77802-2898

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Fax: (979) 776-3805

**EXHIBIT 11**

**From:** Jennifer Waite  
**Sent:** 5/8/2007 3:16:54 PM  
**To:** Karl Gu  
**CC:** Dorothy Branco; Andrea Desrosiers  
**Subject:** RE: CD4 dll and doc

Hi Karl,

Dorothy won't be available to work on the DLL until a bit later this week... Thursday or Friday. We should have it ready for you by early next week. I will update the document and send it to you by Friday.

-Jen

Jennifer Waite  
Software Engineer  
PointCare Technologies, Inc.  
tel: (508) 281-6926 x15  
fax: (508) 281-6930  
[jwaite@pointcare.net](mailto:jwaite@pointcare.net)

-----Original Message-----

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]  
Sent: Tuesday, May 08, 2007 10:52 AM  
To: Jennifer Waite  
Subject: CD4 dll and doc

Hi Jen,

Could you make sure to send me the updated CD4 dll and doc by this Friday? I have a plan to get CD4 Service software finished by then.

Thanks,  
Karl

## **EXHIBIT 12**

**From:** Jennifer Waite  
**Sent:** 5/11/2007 8:52:56 PM  
**To:** Karl Gu  
**CC:**  
**Subject:** RE: LIS dll updated

Hi Karl,

Attached is the updated CD4 DLL document. Dorothy is working on the implementation concurrently with a higher priority project. We hope to have it ready for you by the end of next week.

I tried my best to test the LIS DLL you sent me on Monday. I finally got the cable I needed. I tried this test on 2 different computers and got the same outcome. The UI is telling me the port is initializing properly, but the computer running the simulator is not getting any data...even when I tried to transfer a CBC patient result (which was working in TX!). The UI seems to be creating correct .RES files (see below) but the DLL doesn't seem to be picking them up from the C:\Excell24\Lis\Results directory. I get the following error message right before the VB LisCheckError() function clears out the folder. "Error communicating with LIS. Please check transfer settings and connection."

Everything is leading me to believe it's a problem with the DLL. Have you tried transferring a CBC patient result from the computer attached to the instrument I was working on... using this same DLL?

Here are 2 .RES files created by the UI...one for CBC control, one for CD4 control.

[2] [Demographics]

LOT\_NUMBER=XP057

LOT\_EXPIRE=20070702

CONTROL\_LEVEL=High

TEST\_TIME=20070430121840

[Results]

Test=WBC;20.9;16.5;21.5;K/ $\mu$ L;

Test=Neut;16.2;10.9;13.9;K/ $\mu$ L;

Test=Lymp;3.4;3.1;6.5;K/ $\mu$ L;

Test=Mono;0.9;0.5;2.3;K/ $\mu$ L;

Test=Eos;0.3;0.0;0.8;K/ $\mu$ L;

Test=Bas;0.1;0.0;0.4;K/ $\mu$ L;

Test=Neut%;77.3;57.2;73.2;%;

Test=Lymp%;16.2;15.1;33.1;%;

Test=Mono%;4.4;2.6;12.6;%;

Test=Eos%;1.4;0.0;4.2;%;

Test=Bas%;0.7;0.0;2.0;%;

Test=RBC;3.74;5.42;6.02;M/ $\mu$ L;

Test=Hgb;19.0;18.2;19.8;g/dL;

Test=Hct;37.0;51.0;58.0;%;

Test=MCV;98.8;90.2;100.2;fL;

Test=MCH;50.9;31.7;34.7;pg;

Test=MCHC;51.5;32.6;37.2;g/dL;

Test=RDW;12.6;12.7;16.7;%;

Test=Plt;496;540;700;K/ $\mu$ L;

Test=MPV;8.8;7.1;10.1;fL;

Alert=000100000100000

Flag=000000000000000

[4] [Demographics]

LOT\_NUMBER=CT1083055

LOT\_EXPIRE=20081031

CONTROL\_LEVEL=Normal

TEST\_TIME=20070430152305

[Results]

Test=WBC;20.8;16.5;21.5;K/ $\mu$ L;

Test=Lymp;3.4;3.1;6.5;K/ $\mu$ L;

Test=CD4;7;450;3000;/ $\mu$ L;

Test=Lymp%;16.4;15.1;33.1;%;

Test=CD4%;0.2;0.0;40.0;%;

Alert=000100000100000

Flag=000000000000000

Have a great weekend!

Jen

Jennifer Waite  
Software Engineer  
PointCare Technologies, Inc.  
tel: (508) 281-6926 x15  
fax: (508) 281-6930  
jwaite@pointcare.net

-----Original Message-----

From: Karl Gu [mailto:kgu@mwi-danam.com]  
Sent: Monday, May 07, 2007 11:08 AM  
To: Jennifer Waite  
Subject: LIS dll updated

Hi Jen,

Please check if the attached dll works for CD4 control. It expecting the CD4 control type as [4] and have the same type of header as CBC control with CD4 and CD4% results in the transfer file.

Regards,

Karl

Attachment: CD4 DLL Integration v4.doc

**AuRICA HT ExcellCD4.dll Integration v4**  
**Jennifer Waite 5/11/2007**

### 1. Loading CD4 Algorithm Parameters: LoadCD4Parameters()

At UI startup, the CD4 algorithm parameters shall be read by the VB from a table called "CD4 Parameters" in the Excell24.mdb database and put in a variable of type "CD4\_Algorithm\_Params" which shall defined as follows:

```
Type CD4_Algorithm_Params
    Coefficient as Single
    Offset as Integer
    X_Center_Max as Integer
    X_Center_Min as Integer
    Y_Center_Max as Integer
    Y_Center_Min as Integer
    Lymph_X_Default as Integer
    Lymph_Y_Default as Integer
    Default_Height as Integer
    Default_Width as Integer
    Height_Change as Integer
    Width_Change as Integer
    CD4_X_Max As Integer
    CD4_X_Min As Integer
    dummy As Integer
End Type
```

The VB UI shall provide an interface for Service Technicians to set the CD4 algorithm parameters for both patient samples and CD4 control samples and save it to the database.

After the CD4 sequence is complete, a local instance of the CD4\_Algorithm\_Parameters structure shall be passed to ExcellCD4.dll, along with the FCS file name, through the LoadCD4Parameters() function call. The return value shall be an Integer indicating success (1), failure (0), or .fcs file error (2).

#### VB Function Declaration:

```
Public Declare Function LoadCD4Params Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef CD4_Patient_Parms As
CD4_Algorithm_Parameters, ByVal CD4FCSFileId As String, ByVal
SampleType As Integer) As Integer
```

#### VB Function Call:

```
'CD4 Patient
Status = LoadCD4Parameters(CD4_Patient_Parms, strFCSFileCD4, 0)
OR
'CD4 Low Control
Status = LoadCD4Parameters(CD4_Control_Parms, strFCSFileCD4, 1)
OR
'CD4 Normal Control
Status = LoadCD4Parameters(CD4_Control_Parms, strFCSFileCD4, 2)
```

C++ Function Declaration:

```
int LoadCD4Params(CD4_Algorithm_Parms *pCD4PatientParams, char *
FCSFileName, short SampleType);
```

C++ Struct Definition:

```
struct CD4_Algorithm_Parms
{
    float Coefficient;
    short Offset;
    short X_Center_Max;
    short X_Center_Min;
    short Y_Center_Max;
    short Y_Center_Min;
    short Lymph_X_Default;
    short Lymph_Y_Default;
    short Default_Height;
    short Default_Width;
    short Height_Change;
    short Width_Change;
    short CD4_X_Max;
    short CD4_X_Min;
    short dummy;
};
```

LoadCD4Parameters() will pack the header of the CD4.fcs file with the CD4 algorithm parameter names and values.

## 2. Function to read CD4 cell data and calculate results: ReadCD4Results()

This function shall be defined in ExcellCD4.dll and called by the Service Software during the sequence after the CD4.fcs file is made, or by the VB UI right before displaying new results. The return value shall be an Integer indicating success (1), failure (0), or .fcs file error (2). LoadCD4Parameters() must be called prior to calling this function. After completing the calculation on the CD4 data, the ReadCD4Results() function will store the populated Classification array and Sample structure back into the .FCS file for later results retrieval.

VB Function Declaration:

```
Public Declare Function ReadCD4Results Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef WideAngleCD4 As Byte, _
ByRef ExtinctionCD4 As Byte, _
ByRef SmallAngleCD4 As Byte, _
ByRef SuperWideAngleCD4 As Byte, _
ByRef ClassificationCD4 As Byte, _
ByRef CalculatedResultsCD4 As Calculated_CD4, _
ByVal CD4FCSFileId As String, _
ByVal WBCCount As Single, _
```

```
ByVal NeutCount As Single,
ByVal LYMCount As Single,
ByVal MonoCount As Single,
ByVal CBCFlags As Long) As Integer
```

VB Function Call:

```
Status = ReadCD4Results(WideAngleCD4(0), ExtinctionCD4(0),
SmallAngleCD4(0), SuperWideAngleCD4(0), ClassificationCD4(0),
CalculatedResultsCD4, strCD4FCS, CalculatedResults.result(0),
CalculatedResults.result(1), CalculatedResults.result(2),
CalculatedResults.result(3), CalculatedResults.Flags)
```

VB Definitions and Declarations of Parameters Passed to ReadCD4Results():

```
Type Calculated_CD4
    CD4Result As Single
    CD4PercentResult As Single
    CD4Flags As Long
    total_cell_count As Single
    initial_cell_rate As Single
    final_cell_rate As Single
End Type

Public CalculatedResultsCD4 As Calculated_CD4
```

The initial\_cell\_rate and final\_cell\_rate are calculated using timing data for each event during the first 3 and last 3 seconds of the 15 second acquisition time.

```
Public ClassificationCD4(49999) As Byte
```

Each element in the Classification array represents each cell in total\_cell\_count. A value of 0 in the array represents a non-lymph, 2 is CD4-, 6 is CD4+

```
Public WideAngleCD4(49999) As Byte
Public SmallAngleCD4(49999) As Byte
Public ExtinctionCD4(49999) As Byte
Public SuperWideAngleCD4(49999) As Byte
```

These arrays contain event data binned to 256.

The rest of the parameters passed into the ReadCD4Results() function are values calculated by the CBC algorithm and passed in by value. The CBC algorithm must be run prior to the ReadCD4Results() call.

C++ Function Declaration:

```
int ReadCD4Results(BYTE *pWideAngle,
                    BYTE *pExtinction,
                    BYTE *pSmallAngle,
                    BYTE *pSuperWideAngle,
                    BYTE *pClassification,
```

```

        Sample * pCalculated,
        char * FCSFileName,
        float WBCCount,
        float NeutCount,
        float LymCount,
        float MonoCount,
        long CBCFlags);

```

C++ Struct Definition:

```

struct Sample
{
    float CD4Result;
    float CD4PercentResult;
    long Flags;
    float total_cell_count;
    float initial_cell_rate;
    float final_cell_rate;
};

```

**3. Function to retrieve previously calculated CD4 results:  
RecoverCD4Results()**

This function shall be defined in ExcellCD4.dll and called by the VB UI when displaying previously calculated results. The return value shall be an Integer indicating success (1), failure (0), or .fcs file error (2). LoadCD4Parameters() should NOT be called prior to calling this function. The RecoverCD4Results() function shall read the Classification array and Sample structure that were previously saved in the .FCS file.

All parameters to this function are described in the previous section.

VB Function Declaration:

```

Public Declare Function RecoverCD4Results Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef WideAngleCD4 As Byte, _
    ByRef ExtinctionCD4 As Byte, _
    ByRef SmallAngleCD4 As Byte, _
    ByRef SuperWideAngleCD4 As Byte, _
    ByRef ClassificationCD4 As Byte, _
    ByRef CalculatedResultsCD4 As Calculated_CD4, _
    ByVal CD4FCSFileDialog As String) As Integer

```

VB Function Call:

```

Status = RecoverCD4Results(WideAngleCD4(0), ExtinctionCD4(0),
SmallAngleCD4(0), SuperWideAngleCD4(0), ClassificationCD4(0),
CalculatedResultsCD4, strCD4FCS)

```

C++ Function Declaration:

```
int RecoverCD4Results(BYTE *pWideAngle,  
                      BYTE *pExtinction,  
                      BYTE *pSmallAngle,  
                      BYTE *pSuperWideAngle,  
                      BYTE *pClassification,  
                      Sample * pCalculated,  
                      char * FCSFileName);
```

**EXHIBIT 13**

Peter, can you clear up the concern Karl has regarding the software he's been waiting on for such a long time now. He's getting frustrated. still waiting, putting in long hours on all the work we've loaded him down with.

Thanks,

Doug.

---

From: Karl Gu  
Sent: Friday, May 18, 2007 1:35 PM  
To: Andrew Kenney; Doug Nickols; Gary Young  
Subject: FW: LIS dll updated

Hello,

After all the help I gave to Pointcare, I was expecting in a couple of weeks to have a CD4 software ready for validation. Originally I thought that Pointcare is late for another one week for the part I am requesting. It seems to me that I did not really understand what's going on in their side. They are working on a higher priority project as they said in the mail.

Regards,  
Karl

---

From: Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
Sent: Friday, May 11, 2007 3:53 PM  
To: Karl Gu  
Subject: RE: LIS dll updated

Hi Karl,

Attached is the updated CD4 DLL document. Dorothy is working on the implementation concurrently with a higher priority project. We hope to have it ready for you by the end of next week.



**EXHIBIT 14**

---

From: William Ross  
Sent: Wednesday, May 30, 2007 8:46 AM  
To: Doug Nickols; Gary Young; George Chappell  
Subject: FW: HT Software  
Importance: High

Let me know when the smoke clears on this.....

---

From: Peter Hansen [mailto:[phansen@pointcaretechnologies.com](mailto:phansen@pointcaretechnologies.com)]  
Sent: Tuesday, May 29, 2007 6:01 PM  
To: Gary Young; William Ross; Karl Gu; Doug Nickols  
Cc: Don Barry; Andrea Desrosiers; Jennifer Waite; Dorothy Branco  
Subject: HT Software  
Importance: High

Hello All,

We have hit a snag in the HT project schedule. Here is the situation.

As you know we are behind schedule on the HT because the CD4 subsystem still has hardware problems. Amy has made a lot of progress in finding the problems and solving them. In the end we will be OK, but what has happened from a schedule perspective is not OK.

The HT was scheduled to be ahead of our AuRICA NOW C2/PCT project at all times, but in fact the HT has slipped to the point where the NOW is significantly ahead of the HT. Consequently, whatever is happening on the HT these days is happening at the very point where we are very busy with the NOW. If all had gone to plan on the HT, we would have had no conflict for resources.

The main conflict for resources is in software. I will have to stop HT software work at PCT for approximately 2 1/2 weeks from today in order to meet long standing, scheduled obligations for our software group on the NOW. I will work with the group to find a way to minimize the

overall HT schedule impact.

In the meantime please understand that the critical path for this project still lies through solving the hardware problems in the CD4 subsystem, and not through software. No system validation is possible until those problems are solved. When we met last at Drew I believe that was well understood by Gary and George and they have been responsive to the needs of the project.

I will ask Don Barry to send Gary the most recent schedule revision in our PCT Development Plan for discussion. It is still valid and acceptable to us despite any hold ups in software.

If there are any questions in this matter please contact me directly. My mobile is 518 253 8643. I am frequently out and about and away from my desk phone.

By the way I don't mean to annoy anyone by asking for a read confirmation, but you all have such a wide variety of emailboxes ranging from Escalon, to MWI Danam, to Drew, to ATT that I am never sure that I hit them right.

Thank you,

Peter

## **EXHIBIT 15**

**From:** Jennifer Waite  
**Sent:** 6/2/2007 10:04:51 PM  
**To:** Jennifer Waite; Williamross7@tx.rr.com; Karl Gu  
**CC:** Andrea Desrosiers  
**Subject:** RE: CD4 UI

William and Karl,

Please read the email below. It was returned to me by our server because my attachment size was too big. I have placed the 2 .zip files onto our FTP site so that you can download them. Our ftp site is <ftp://webmail.pointcare.net>. You can log in with user name "drewsci" and password "cowboys". The files are in the "CD4 UI 1-Jun-07" directory.

Have a great weekend!

Jen

---

**From:** Jennifer Waite  
**Sent:** Fri 6/1/2007 7:35 PM  
**To:** 'Williamross7@tx.rr.com'; 'Karl Gu'  
**Cc:** Andrea Desrosiers  
**Subject:** CD4 UI

Hi William and Karl,

I have attached a zip file containing the necessary files for installing the UI, which you can use to start testing. Just launch the install.bat file. Most (see list below) Hematology and CD4 functions should work, but you will not get meaningful CD4 data, as we discussed yesterday with Peter on the phone. Please be aware that due to the current state of the CD4 dll, anytime you view CD4 results you will have about a 3 to 7 second delay before the results are actually shown.

When you install the UI, a populated Excell24.mdb database and many sample data files will be installed so you can immediately start testing many functions without having to run samples. If you would like default (empty) databases, you will find them in the C:\Excell24\Datasets directory called Excell24\_Template.mdb and XL24Setup\_XL24\_Template.mdb. You just have to rename them before use. There are no user passwords set up in the populated Excell24.mdb database. If you use the empty database, the Service user password is "service".

The second zip file I attached to this email contains the updated Control Utility program and

accompanying source code and database.

Here is a list of UI tasks that still need to be completed:

1. STAT function needs more debugging. It doesn't work correctly at this time.
2. UPS support
3. Waiting for a few more button icon images from Dennis Chappell
4. Modify a few function calls when Dorothy updates ExcellCD4.dll.
5. Add support for CD4 flags (this won't happen until we can get meaningful CD4 data).
6. Need to fix the CD4 Control barcode label. The barcode is too small on the current label to be automatically read by the Auto Sampler.
7. Drew needs to supply new Main Screen logo image (Designed by Dennis?)
8. Need to add option on Operation Setup screen for 24-Hour time display throughout the UI. This was requested by Peter.
9. Language translation, testing, and accompanying screen adjustments.
10. Update Peer Review Utility (Karl mentioned this to me briefly while I was in TX. I do not have the code).

As far as documentation is concerned, I owe you guys an updated SRS (requirements document), as well as an updated Validation document with the CD4 functions added in.

I do not know at this time when these tasks will be complete because for the next 2 weeks I will be working on our AuRICA NOW software validation which includes me going to France for a week. I will, of course, be reachable at any time through email.

Please don't hesitate to contact me with any questions.

Best Regards,

Jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

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fax: (508) 281-6930

jwaite@pointcare.net

## **EXHIBIT 16**

**From:** Karl Gu  
**Sent:** 6/8/2007 3:49:09 PM  
**To:** Gary Young; Doug Nickols  
**CC:**  
**Subject:** FW: CD4 Update

Pointcare delivered the software and we will start testing ASAP.

Karl

---

**From:** Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
**Sent:** Friday, June 08, 2007 10:20 AM  
**To:** Karl Gu; [Williamross7@tx.rr.com](mailto:Williamross7@tx.rr.com)  
**Cc:** Andrea Desrosiers; Dorothy Branco  
**Subject:** CD4 Update

Hi Karl and William,

The attached zip file contains a new CD4 DLL file, a new UI executable file, and the CD4 DLL integration document. Dorothy has completed the DLL changes that we discussed in TX and is described in the document. The UI executable has changed to support the new RecoverCD4Results() function call.

Karl, I finally figured out why I was having LIS communication problems a couple of weeks ago. The reason is that I didn't know I needed a "null modem" cable. I finally found one and tested your DLL. I tested transferring a CD4 control result file and everything is working correctly as far as I can tell.

Also, Karl, could you make a small change to Hematology24.dll for us? We noticed that when you are creating the CD4 .fcs file, you are writing junk (left over) data into the part of the file that holds classification data. Could you make it a point to pack zeros into this part of the file? The reason is that we don't want to have false classification values in the file at any time... in case the software crashes or is terminated for some unknown reason before the CD4 dll has a chance to touch the file and reset that data. Let me know if you need clarification.

Thanks...and have a great weekend!

-Jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

tel: (508) 281-6926 x15

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jwaite@pointcare.net

Attachment: CD4 DLL & DLL Update 8Jun07.zip

**AuRICA HT ExcellCD4.dll Integration v5**  
**Jennifer Waite 6/7/2007**

### 1. Loading CD4 Algorithm Parameters: LoadCD4Parameters()

At UI startup, the CD4 algorithm parameters shall be read by the VB from a table called "CD4 Parameters" in the Excell24.mdb database and put in a variable of type "CD4\_Algorithm\_Params" which shall defined as follows:

```
Type CD4_Algorithm_Params
    Coefficient as Single
    Offset as Integer
    X_Center_Max as Integer
    X_Center_Min as Integer
    Y_Center_Max as Integer
    Y_Center_Min as Integer
    Lymph_X_Default as Integer
    Lymph_Y_Default as Integer
    Default_Height as Integer
    Default_Width as Integer
    Height_Change as Integer
    Width_Change as Integer
    CD4_X_Max As Integer
    CD4_X_Min As Integer
    dummy As Integer
End Type
```

The VB UI shall provide an interface for Service Technicians to set the CD4 algorithm parameters for both patient samples and CD4 control samples and save it to the database.

After the CD4 sequence is complete, a local instance of the CD4\_Algorithm\_Parameters structure shall be passed to ExcellCD4.dll, along with the FCS file name, through the LoadCD4Parameters() function call. The return value shall be an Integer indicating success (0), failure (1), or .fcs file error (2).

#### VB Function Declaration:

```
Public Declare Function LoadCD4Params Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef CD4_Patient_Parms As
CD4_Algorithm_Parameters, ByVal CD4FCSFileId As String, ByVal
SampleType As Integer) As Integer
```

#### VB Function Call:

```
'CD4 Patient
Status = LoadCD4Parameters(CD4_Patient_Parms, strFCSFileCD4, 0)
OR
'CD4 Low Control
Status = LoadCD4Parameters(CD4_Control_Parms, strFCSFileCD4, 1)
OR
'CD4 Normal Control
Status = LoadCD4Parameters(CD4_Control_Parms, strFCSFileCD4, 2)
```

C++ Function Declaration:

```
int LoadCD4Params(CD4_Algorithm_Parms *pCD4PatientParams, char *
FCSFileName, short SampleType);
```

C++ Struct Definition:

```
struct CD4_Algorithm_Parms
{
    float Coefficient;
    short Offset;
    short X_Center_Max;
    short X_Center_Min;
    short Y_Center_Max;
    short Y_Center_Min;
    short Lymph_X_Default;
    short Lymph_Y_Default;
    short Default_Height;
    short Default_Width;
    short Height_Change;
    short Width_Change;
    short CD4_X_Max;
    short CD4_X_Min;
    short dummy;
};
```

LoadCD4Parameters() will pack the header of the CD4 .fcs file with the CD4 algorithm parameter names and values.

## 2. Function to read CD4 cell data and calculate results: ReadCD4Results()

This function shall be defined in ExcellCD4.dll and called by the Service Software during the sequence after the CD4 .fcs file is made, or by the VB UI right before displaying new results. The return value shall be an Integer indicating success (0), failure (1), or .fcs file error (2). LoadCD4Parameters() must be called prior to calling this function. After completing the calculation on the CD4 data, the ReadCD4Results() function will store the populated Classification array and Sample structure back into the .FCS file for later results retrieval.

VB Function Declaration:

```
Public Declare Function ReadCD4Results Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef WideAngleCD4 As Byte, _
ByRef ExtinctionCD4 As Byte, _
ByRef SmallAngleCD4 As Byte, _
ByRef SuperWideAngleCD4 As Byte, _
ByRef ClassificationCD4 As Byte, _
ByRef CalculatedResultsCD4 As Calculated_CD4, _
ByVal CD4FCSFileDialog As String, _
ByVal WBCCount As Single, _
```

```
    ByVal NeutCount As Single, _
    ByVal LYMCount As Single, _
    ByVal MonoCount As Single, _
    ByVal CBCFlags As Long) As Integer
```

VB Function Call:

```
Status = ReadCD4Results(WideAngleCD4(0), ExtinctionCD4(0),
SmallAngleCD4(0), SuperWideAngleCD4(0), ClassificationCD4(0),
CalculatedResultsCD4, strCD4FCS, CalculatedResults.result(0),
CalculatedResults.result(1), CalculatedResults.result(2),
CalculatedResults.result(3), CalculatedResults.Flags)
```

VB Definitions and Declarations of Parameters Passed to ReadCD4Results():

```
Type Calculated_CD4
    CD4Result As Single
    CD4PercentResult As Single
    CD4Flags As Long
    total_cell_count As Single
    initial_cell_rate As Single
    final_cell_rate As Single
End Type
```

```
Public CalculatedResultsCD4 As Calculated_CD4
```

The initial\_cell\_rate and final\_cell\_rate are calculated using timing data for each event during the first 3 and last 3 seconds of the 15 second acquisition time.

```
Public ClassificationCD4(49999) As Byte
```

Each element in the Classification array represents each cell in total\_cell\_count. A value of 0 in the array represents a non-lymph, 2 is CD4-, 6 is CD4+

```
Public WideAngleCD4(49999) As Byte
Public SmallAngleCD4(49999) As Byte
Public ExtinctionCD4(49999) As Byte
Public SuperWideAngleCD4(49999) As Byte
```

These arrays contain event data binned to 256.

The rest of the parameters passed into the ReadCD4Results() function are values calculated by the CBC algorithm and passed in by value. The CBC algorithm must be run prior to the ReadCD4Results() call.

C++ Function Declaration:

```
int ReadCD4Results(BYTE *pWideAngle,
                    BYTE *pExtinction,
                    BYTE *pSmallAngle,
                    BYTE *pSuperWideAngle,
                    BYTE *pClassification,
```

```

        Sample * pCalculated,
        char * FCSFileName,
        float WBCCCount,
        float NeutCount,
        float LymCount,
        float MonoCount,
        long CBCFlags);

```

C++ Struct Definition:

```

struct Sample
{
    float CD4Result;
    float CD4PercentResult;
    long Flags;
    float total_cell_count;
    float initial_cell_rate;
    float final_cell_rate;
};

```

**3. Function to retrieve previously calculated CD4 results:**  
**RecoverCD4Results()**

This function shall be defined in ExcellCD4.dll and called by the VB UI when displaying previously calculated results. The return value shall be an Integer indicating success (0), failure (1), or .fcs file error (2). LoadCD4Parameters() should NOT be called prior to calling this function. The RecoverCD4Results() function shall read the Classification array and Sample structure that were previously saved in the .FCS file.

All parameters to this function are described in the previous section.

VB Function Declaration:

```

Public Declare Function RecoverCD4Results Lib
"C:\windows\system32\ExcellCD4.dll" (ByRef WideAngleCD4 As Byte, _
    ByRef ExtinctionCD4 As Byte, _
    ByRef SmallAngleCD4 As Byte, _
    ByRef SuperWideAngleCD4 As Byte, _
    ByRef ClassificationCD4 As Byte, _
    ByRef CalculatedResultsCD4 As Calculated_CD4, _
    ByVal CD4FCSFileDialog As String) As Integer

```

VB Function Call:

```

Status = RecoverCD4Results(WideAngleCD4(0), ExtinctionCD4(0),
SmallAngleCD4(0), SuperWideAngleCD4(0), ClassificationCD4(0),
CalculatedResultsCD4, strCD4FCS)

```

C++ Function Declaration:

```
int RecoverCD4Results(BYTE *pWideAngle,  
                      BYTE *pExtinction,  
                      BYTE *pSmallAngle,  
                      BYTE *pSuperWideAngle,  
                      BYTE *pClassification,  
                      Sample * pCalculated,  
                      char * FCSFileName);
```

**EXHIBIT 17**

**From:** Jennifer Waite  
**Sent:** 6/8/2007 8:59:27 PM  
**To:** Karl Gu  
**CC:**  
**Subject:** RE: CD4 Update

Sorry about that! I guess we were looking at a really old file created by the 2280 machine using manual prep methods. Nevermind!!

Jennifer Waite  
Software Engineer  
PointCare Technologies, Inc.  
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fax: (508) 281-6930  
jwaite@pointcare.net

-----Original Message-----

From: Karl Gu [mailto:[kgu@mwi-danam.com](mailto:kgu@mwi-danam.com)]  
Sent: Friday, June 08, 2007 1:29 PM  
To: Jennifer Waite; [Williamross7@tx.rr.com](mailto:Williamross7@tx.rr.com)  
Cc: Andrea Desrosiers; Dorothy Branco  
Subject: RE: CD4 Update

Hi Jen,

I checked Hematology24.dll code. The classification for CD4 is set as 0 all the time when store to disk. I am not sure why you have any junk data.

Karl

From: Jennifer Waite [mailto:[jwaite@pointcaretechnologies.com](mailto:jwaite@pointcaretechnologies.com)]  
Sent: Friday, June 08, 2007 10:20 AM  
To: Karl Gu; Williamross7@tx.rr.com  
Cc: Andrea Desrosiers; Dorothy Branco  
Subject: CD4 Update

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Thanks...and have a great weekend!

-Jen

Jennifer Waite

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